U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6201–6240

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or granting a motion for summary judgment, and (2) criminal proceedings terminated upon pleas of guilty or nolo contendere. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

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GEO. P. LARRICK, *Commissioner of Food and Drugs.*

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*For presence of a habit-forming substance without warning statements, see No. 5707; omission of, or unsatisfactory, ingredients statements, Nos. 6204, 6205, 6227; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6204, 6205; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6204, 6205, 6208, 6237; cosmetic, actionable under the drug provisions of the Act, No. 6213.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6201–6240

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopeia) and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative, and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug; and (2) the drug was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; 502(f)(1), the labeling of the article failed to bear adequate directions for use; Section 502(l), the article was composed in part of penicillin and streptomycin sulfate, and it was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6201. Andriol and Andriol E. (F.D.C. No. 44550. S. Nos. 99–842/3 P.)

QUANTITY: 54 1-oz. btls. of *Andriol* and 60 1-oz. btls. of *Andriol E* at Minneapolis, Minn., in possession of Frommes Method, Inc.

SHIPPED: The chemical substances contained in the articles, namely, "Delta 5-Androstene-3 beta, 17 beta Diol" and "Delta 5-Androstene-3 beta, 17 beta Diol Dipropionate," were shipped from Chicago, Ill., prior to the filing of the libel.

LABEL IN PART: (Btl.) "The Frommes Formula Andriol [or "Andriol E"] by Frommes Scalp Specialists, Minneapolis."

RESULTS OF INVESTIGATION: McDonald Laboratories, St. Paul, Minn., manufactured the *Andriol* from the chemical substances shipped in interstate commerce as described above. In addition, isopropyl alcohol was added to the article. Thereafter, the article labeled "*Andriol*" was sold to Frommes Method, Inc., who repacked a portion of the article into 1-oz. bottles. The Frommes Method, Inc., manufactured the *Andriol E* by adding tyrosine, l-lysine, and powdered pine odor to the *Andriol*, and packing such article into 1-oz. bottles.

The above-quoted chemical substances of the articles were new drug substances. The article of *Andriol* was sold and shipped to Frommes Method, Inc.,

by McDonald Laboratories without an effective new drug application and Frommes Method, Inc., did not have a new drug application for the repacked articles.

LIBELED: 5–2–60, Dist. Minn.

CHARGE: 505(a)—the articles were new drugs within the meaning of the law, and applications filed pursuant to the law were not effective with respect to the drugs.

DISPOSITION: 6–14–60. Default—destruction.

6202. Pega Palo. (F.D.C. No. 42518. S. No. 14–916 P.)

QUANTITY: 68 ½-lb. paper bags at Canton, Ohio.

SHIPPED: On an unknown date from the Dominican Republic.

LABEL IN PART: "PEGA PALO Bring to a boil one gallon of water, add one teaspoon of powder, cook for one hour in stainless pot with lid, take one ounce with each meal."

RESULTS OF INVESTIGATION: The article was being distributed by Durwood Drew Roberts during the course of lectures given by him at Canton, Ohio.

LIBELED: 12–2–58, N. Dist. Ohio.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use as a gland aid, which was the condition for which it was offered orally by Durwood Drew Roberts; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application pursuant to law was not effective with respect to such drug.

DISPOSITION: On 1–3–59, Durwood Drew Roberts, claimant, filed an answer denying that the article was misbranded or a new drug. In addition, the claimant filed a motion to quash service on the grounds that the "Summons on Libel of Information and Forfeiture" and unsigned "Libel of Information" was served in the M. Dist. Pa., by the United States Marshal of that district and was therefore without force and effect. The court overruled the motion to quash on 3–6–59.

Thereafter, the Government filed requests for admissions, which were not answered, and on 6–13–60, a default decree was entered ordering the destruction of the article.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

DRUG FOR VETERINARY USE

6203. Trace's Poultry and Animal Booster. (F.D.C. No. 44410. S. No. 69–006 P.)

QUANTITY: 37 3½-lb. tins at Slayton, Minn., in possession of the Slayton Drug Store.

SHIPPED: 1–23–60, from Madison, S. Dak.

LABEL IN PART: (Tin) "Trace's Hi-Potency Water Soluble Poultry and Animal Booster * * * Guaranteed Analysis Penicillin 3.25 gm. per lb. Streptomycin Sulphate 2 gm. per lb. Terramycin Oxytetracycline Hydrochloride 1.25 gm. per lb. Vitamin B_{12} 1 mg. per lb. Vitamin A 500,000 USP Units per lb. Vitamin D_3 400,000 ICU per lb. Niacin 2,000 mg. per lb. Riboflavin 500 mg. per lb. Pantothenic Acid 500 mg. per lb. Menadione (Vitamin K) 100 mg. per lb. Pyridoxine Hydrochloride 100 mg. per lb. Thiamine Hydrochloride B_1 2,000

mg. per lb. Alphatocopherol (Vit. E) 200 mg. per lb. Ascorbic Acid (Vit. C) 200 mg. per lb."

RESULTS OF INVESTIGATION: The article was shipped unlabeled as described above and after its receipt by the dealer at Slayton, Minn., the tins containing the article were labeled with the above-mentioned labels.

LIBELED: 3–28–60, Dist. Minn.

CHARGE: 502(a)—the label of the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment and preventive of all diseases in poultry, hogs, calves, lambs, dogs, cats, and mink; and 502(l)—the article was a drug composed in part of penicillin and streptomycin sulfate and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507 in that certification of the article under the above-mentioned label had not been obtained.

DISPOSITION: 5–11–60. Consent—claimed by Tracy L. Hafner, t/a Tracy Hafner Slayton Drug Store, and released for relabeling.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6204. Seconal Sodium capsules and amphetamine tablets. (F.D.C. No. 43585. S. No. 66–005 P.)

QUANTITY: 50,000 tablets of amphetamine and 1,000 capsules of Seconal Sodium at Stamford, Conn.

SHIPPED: On or about 10–8–59, from New Jersey to Connecticut, by Charles W. Christiansen, also known as Charlie Benjamin.

LIBELED: On or about 10–8–59, Dist. Conn.

CHARGE: 502(b)—the articles failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(d)—the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, and their label failed to bear the name, and quantity, or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; 502(e)(1)—the labels of the articles failed to bear the common or usual names of the articles; 502(f)(1)—the labeling of the articles failed to bear adequate directions for use and they were not exempt from such requirement since the articles were in possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage or wholesale distribution of prescription drugs and since the articles were not to be dispensed as required by 503(b)(1); and 503(b)(4)—the articles were subject to 503(b)(1) and their labeling failed to bear the mandatory statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6–28–60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6205. Various drugs. (F.D.C. No. 44590. S. Nos. 19–841 R, 19–843 R, 19–846 R, 19–851/4 R, 19–856 R, 19–858/9 R, 19–861 R, 19–864 R, 19–868/70 R, 19–872 R, 19–875 R, 19–877 R, 19–881 R, 21–067/71 R, 21–073/4 R, 21–077 R, 21–079 R, 21–083 R, 21–087/8 R, 21–093/4 R, 21–097 R, 21–099/100 R, 21–103 R, 21–107 R, 21–110/11 R, 21–113 R, 21–117/19 R, 21–122 R.)

*See also Nos. 6202, 6204.

QUANTITY: About 644 lbs. of various quantities of bulk and repackaged herbal preparations and other drugs at Detroit, Mich., in possession of W.E.B. Chemical & Products Co. The repackaged herbal preparations and drugs consisted of articles labeled in part *"Potter's Paste" or "Potter's Cream," "Brain Herb Tonic," "Kidney Tonic," "Special Palsy Tonic," "Prostate Gland Tonic," "Red Blood Tonic," "Brown's Appetite Tonic," "Brown's Black Liquid," "Brown's Blood Circulation Tonic," "Building-Up Tonic," "Cramp Bark Herb Tonic," "Golden Seal Tonic," "Herb Laxative," "Heart Tonic," "Marvelous Nerve Tonic," "Ringworm Extract," "For Sinus," "Varicose Veins Tonic," "Brain Herb Tonic Tea," "For External Cataract," "Diabetes Herb Tea," "Herbs for Douche," "Hardening of the Arteries Herb Tea," "Special Blood Herb Tea," "Tapeworm Tea," "Appetite Herb Tea," "Bed-Wetting Herb Tea," "Building-Up Herb Tea," "Dropsy Herb Tea," "Eczema Herb Tea," "Gruel," "Hay Fever," "For Hiccough," "Kidney Herb Tea," "Laxative Tea," "Herb Tea for Monthly Trouble," "Prostate Gland Herb Tea," "For a Wash for Skin Ailments," "Herb Tea for Sleeplessness," "Herb Tea to Stop Vomiting," "Iodine Ration Capsules," "Stimulant Capsules," "Reducing Capsules," "Special Cream."*

The bulk herbal preparations and drugs consisted of Beech bark, Beech leaves, bloodroot (whole), Black Willow bark, bloodroot (cut), goldenseal, mandrake, nettle, vinca major, queen's root, Slippery Elm, wintergreen, agrimony, alfalfa seed, alfalfa tea (buffalo herb), American sarsaparilla, bearberry, beth root, black cohosh, black root, Black Walnut leaves, blue flag, boneset, broom tops, brown sugar, burdock, Cajeput oil, camphor, Cascara sagrada extract, camomile, Chestnut leaves, compound cinchona tincture, columbo, comfrey root, corn silk, cramp bark, cubeb (Java pepper), devils-shoestring, dill herb (common dill plant), dog grass (couch grass, quick grass), elecampane, elder flowers (honeysuckle), European centaury, eyebright, fenugreek, figwort, fragrant valerian, gentian root, Jamaica ginger, gobernadora, gravel plant, Grotta's Cold Cream, gold thread (golden thread), Holly leaves, hops, tincture of iodides, Juniper berries, kelp, kola nuts, ladyslipper, lanolin, Licorice root, linden flowers, lobelia, male fern, marshmallow root, Mistletoe, mineral oil, Pareira Brava, Parsley Piert, Peach Tree leaves, phenol, plantain, pleurisy weed (pleurisy root), pokeroot, potassium iodide, Prickly Ash bark, Prickly Ash berries, queen of the meadow, red raspberry leaves, Roman camomile, Roman motherwort, sage, sassafras, saw palmetto, skullcap, sea wrack, senna leaves, shepherd's-purse, skunk cabbage, sodium benzoate, spikenard (spignet), spearmint, sulfathiazole, tansy, Thuja (Tree of Life), turtlebloom, Wafer Ash, wahoo, White Poplar, wild carrot herb, woodbetony, yellow dock, yerba-santa, and almond oil.

SHIPPED: Between 1–8–59 and 2–4–60, from Hammond, Ind.; San Francisco, Calif.; St. Louis, Mo.; New York, N.Y.; Boston, Mass.; New Orleans, La.; Monticello, N.Y.; Philadelphia, Pa.; Indianapolis, Ind.; and Newark, N.J.

ACCOMPANYING LABELING: Loose repack labels, order forms, and price lists headed "We Carry a Full Line of Herb Teas and All Kinds of Herb Tonics."

RESULTS OF INVESTIGATION: The repackaged articles had been repacked and labeled by the dealer from bulk raw materials shipped as described above.

LIBELED: 6–8–60, E. Dist. Mich.

CHARGE: All articles, except the article labeled "Potter's Paste" or "Potter's Cream," 502(a)—while held for sale, the labeling of the articles contained false and misleading representations that the articles were an adequate and effective treatment for external cataracts; arthritis; brain trouble; and "other complaints"; diabetes; hardening of the arteries; heart disease; purifying the blood; impure blood; acid liver; removal of tapeworms; appendicitis; increasing the appetite; asthma; bed-wetting; improving circulation of the blood; tumors; boils; growths; lack of vitality, strength, pep and vigor; change-of-life, or menopause, and menstrual irregularities; diarrhea; dropsy; eczema; epilepsy; improving eyesight; gallstones; improperly functioning glands; ulcerated stomach; hay fever; hemorrhages; hiccough; high blood pressure; diseases of the kidneys; constipation; nervous conditions; rheumatism; muscular conditions; night sweats; pleurisy; prostate trouble; ruptures; skin diseases; sleeplessness; varicose veins; vomiting; removal of all types of worms; goiter; weight reduction; skin eruptions; swelling of joints; bladder troubles; palsy; anemia; wounds; bruises; colds; menstrual cramps and pains; inflammatory conditions; debilitating diseases; ringworm; sinus conditions; kidney stones; irritated and inflamed urinary tract; and ear troubles.

Article labeled in part "*Potter's Paste*" or "*Potter's Cream*," 502(b)—while held for sale, it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of the contents; 502(e)(2)—the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use in the treatment of cancer of the breast, and goiters, diseases for which it was recommended orally at the dealer's retail establishment.

DISPOSITION: 7–8–60. Default—destruction.

6206. "Thermassage" chair. (F.D.C. No. 44423. S. No. 11–713 R.)

QUANTITY: 24 chairs at Chicago, Ill., in possession of the Oxford Chair Co.

SHIPPED: 3–14–60, from Los Angeles, Calif.

RESULTS OF INVESTIGATION: Examination showed that the article was an adjustable, upholstered, reclining chair, containing an electric heating element and a vibrator unit. On the right arm of the chair was a control panel for adjusting the degree of heat and degree of vibration.

LIBELED: 4–4–60, N. Dist. Ill.

CHARGE: 502(f)(1)—the labeling of the article, while held for sale, failed to bear adequate directions for use in overcoming or preventing arthritis, cancer, heart attacks, strokes, kidney conditions, varicose veins, and liver conditions which were the purposes and conditions for which the dealer orally offered the article.

DISPOSITION: 5–4–60. Consent—claimed by Oxford Furniture Distributing Co., Los Angeles, Calif., and relabeled. The decree provided, among other things, that no words, statement, or information required by the Act should be made in labeling or otherwise, except as it appeared in a leaflet entitled "The Oxford Thermassage Chair" which was attached to the decree and made a part thereof.

6207. Jacuzzi Whirlpool Bath. (F.D.C. No. 44573. S. No. 11–817 R.)

QUANTITY: 14 individually cartoned devices at Chicago, Ill., in possession of Hydro-Massage Health, Inc.

SHIPPED: Between 2–10–60 and 3–3–60, from Berkeley, Calif., by Jacuzzi Research, Inc.

LABEL IN PART: (Ctn.) "Jacuzzi Whirlpool Bath."

ACCOMPANYING LABELING: Pamphlet entitled "Hydrotherapy in General Practice * * * reprinted from Modern Medicine February 15, 1950"; a brochure entitled "Now Whirlpool Hydrotherapy for Hospital and Clinic"; and leaflets entitled "The Use of the Whirlpool Bath," "Relaxes—Refreshes—Revitalizes Jacuzzi Whirlpool Bath," and "Reprinted from The Journal of The American Medical Association * * * Brine Bath Treatments for Decubitus Ulcers."

RESULTS OF INVESTIGATION: The article was a portable unit containing an enclosed electric motor which would drive a water pump. Water was forcefully driven through a nozzle and an aspirator, thus producing a swirling air-water foam.

LIBELED: 5–16–60, N. Dist. Ill.

CHARGE: 502(a)—the labeling accompanying the article, when shipped, contained false and misleading representations that the article was an adequate and effective treatment for relieving or overcoming peripheral neuritis; osteoarthritis; chronic gout; myositis; fibrositis; hypertrophic spondylitis; spastic constipation; spastic colitis; pylorospasm; neurasthenia; cerebral arteriosclerosis; convulsions; pruritis; scaly dermatitis; pemphigus; atonic constipation; biliary atony; impotence; vascular spasm; and for preventing deformities of arthritis and rheumatism, and other disease conditions; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use in the treatment of arthritis; multiple sclerosis; cerebral palsy; muscular dystrophy; rheumatoid arthritis; osteoarthritis; traumatic arthritis; third degree burns; cardiac cases; stroke; ulcers; ulcerated skin; mental cases; and for toning and firming the skin and muscles; which were the conditions and purposes for which the article was offered in oral statements made by a representative of the dealer firm.

DISPOSITION: 6–10–60. Consent—claimed by Hydro-Massage Health, Inc., and relabeled.

6208. Mercier's Radioactive device. (F.D.C. No. 44157. S. No. 52–955 P.)

QUANTITY: 6 assembled devices at Scottsdale, Ariz., in possession of A. H. Lee, and a number of component parts of such devices at Glendale, Ariz., in possession of A. F. Mercier. Such component parts consisted of 6 quartz tubes; 8 quartz test tubes; 1 article of plexiglass; 1 article of plexiglass and carbon mixture; 1 brass wire screen; and quantities of radium barium chloride, thorium oxide, and lanthanum oxide.

SHIPPED: The following components of the devices were shipped on unknown dates as follows: the quartz tubes and quartz test tubes from Willoughby, Ohio; the lanthanum oxide and thorium oxide from West Chicago, Ill.; and the radium barium chloride from Denver, Colo.

ACCOMPANYING LABELING: Literature entitled: "Atomic Theory in Molecular Reconstruction"; "A Process Originated to Readjust in proper Order the Law of the Individual as it Relates to the Chemical Balance"; "The Law of Nuclear

Action as it Relates to the Living Substance"; "Einstein's Law of Photo Electric Effect"; and "Blood Test."

RESULTS OF INVESTIGATION: Examination with the use of a beta-gamma survey meter disclosed that the center of the assembled devices possessed radioactivity in the amount of 17 milliroentgens per hour which is about 2 to 3 times that of a radium dial watch.

LIBELED: 1–11–60, Dist. Ariz.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the device was an adequate and effective treatment for arthritis, diabetes, anemia, cancer, numerous bone ailments, to dissolve blood clots and eliminate inflammation through irradiation of a series of samples of a person's blood and the reinjection of the blood plasma after irradiation; 502(b)(1)—the device failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(f)(1)—the labeling failed to bear adequate directions for use for the purposes for which it was intended, namely, the prevention and treatment of epilepsy, lukemia, cancer, arthritis, and mentally retarded children, which were the conditions and diseases for which the device was recommended orally by A. F. Mercier.

DISPOSITION: On 2–24–60, A. F. Mercier appeared as claimant and filed a motion to dismiss, which was denied by the court on 3–15–60. On 3–21–60, the claimant filed a claim and answer denying that the article was misbranded. Thereafter, the Goverment filed interrogatories against the claimant which were answered in part after which the Government filed supplemental interrogatories. On 4–13–60, the Government filed a motion for summary judgment on the ground that there was no genuine issue as to any material fact with respect to the charges of misbranding under 502(b)(1) and 502(f)(1). The motion was granted on 5–6–60, and, on 7–1–60, the articles were ordered condemned and delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6209. Thyroid-digitalis tablets and thyroid tablets. (F.D.C. No. 43708. S. Nos. 23–389/90 P.)

INFORMATION FILED: 4–11–60, S. Dist. Calif., against Joseph L. Jones, t/a J. L. Jones & Co., Sun Valley, Calif.

SHIPPED: 9–18–58 and 10–16–58, from California to Nevada.

LABEL IN PART: (Ctn.) "J. L. JONES & COMPANY Manufacturing Chemists 7200 Vineland Ave., Sun Valley, California MANUFACTURED FOR * * * Each tablet contains: Thyroid U.S.P. 3 grains Digitalis Leaves Powder ¾ grain Plus added excipients 10 = 71 grains * * * IMPORTANT This is a bulk shipment, intended for further processing only." or "J. L. JONES & COMPANY Manufacturing Chemists * * * Each tablet contains: Thyroid 5 grains Plus added excipients 10 = 165 grains * * * S. C. Blue."

RESULTS OF INVESTIGATION: The *thyroid-digitalis tablets* contained about 76 percent of the labeled amount of thyroid and 58 percent of the labeled amount of digitalis per tablet, and the *thyroid tablets* contained about 65 percent of the labeled amount of thyroid per tablet.

CHARGE: 501(c)—the strength of the *thyroid-digitalis tablets* differed from that which they were represented to possess; and 502(a)—the statement "Each tablet contains: Thyroid 5 grains" on the label of the *thyroid tablets* was false and misleading.

The information alleged also that a number of food supplement tablets were adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

PLEA: Nolo contendere.

DISPOSITION: 6–13–60. $750 fine.

6210. Syngesterone (progesterone). (F.D.C. No. 44562. S. Nos. 98–803 P, 996 R, 1–662 R.)

QUANTITY: 350 individually cartoned 10-cc. vials at Chamblee, Ga.

SHIPPED: 12–14–59, from Brooklyn, N.Y., by Chas. Pfizer & Co., Inc.

LABEL IN PART: (Ctn. and vial) "Syngesterone Brand of Progesterone, U.S.P. in aqueous suspension 25 mg./cc. For Intramuscular Use Only * * * Chas. Pfizer & Co., Inc., New York, New York."

ACCOMPANYING LABELING: Leaflet in carton entitled "Syngesterone Brand of Progesterone U.S.P."

RESULTS OF INVESTIGATION: Examination showed that the article contained from 69.7 percent to 124.1 percent of the labeled amount of *progesterone*. The United States Pharmacopeia requires that sterile progesterone suspension contain not less than 93 percent and not more than 107 percent of the labeled amount of *progesterone*.

LIBELED: 5–4–60, N. Dist. Ga.

CHARGE: 501(b)—when shipped, the strength of the article differed from and its quality fell below the standard for "Sterile Progesterone Suspension" set forth in the United States Pharmacopeia; and 502(a)—the name "Syngesterone Brand of Progesterone, U.S.P. in Aqueous Suspension 25 mg./cc." was false and misleading.

DISPOSITION: 6–14–60. Default—destruction.

6211. Vitamin B_{12} injection. (F.D.C. No. 44452. S. No. 27–713 R.)

QUANTITY: 6 10-cc. vials at Davenport, Iowa.

SHIPPED: 3–22–60, from Minneapolis, Minn.

LIBELED: 5–11–60, S. Dist. Iowa.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each cc. contains: Vitamin B_{12} activity * * * equivalent to: Cyanocobalamin 10 Mcg * * * Fortified with vit. B_{12} cryst 100 mcg" was false and misleading as applied to the article which contained less than 50 percent of the declared amount of vitamin B_{12}.

DISPOSITION: 5–27–60. Consent—destruction.

DRUG FOR VETERINARY USE

6212. Egg ration. (F.D.C. No. 44575. S. Nos. 7–045/6 R.)

QUANTITY: 22 100-lb. bags and 6 100-lb. bags at Fairfield, Vt.

SHIPPED: Some time within the 6 months period prior to 5–6–60, from Oneonta, N.Y., by Elmore Milling Co., Inc.

LABEL IN PART: (Bags) "Elmore Complete Market Egg Ration (1A) * * * Arsanilic Acid—0.01% * * * Manufactured by Elmore Milling Company, Inc." and "Elmore Complete Market Egg Ration (1A) * * * 3-Nitro-4 Hydroxyphenylarsonic Acid—0.005% * * * Manufactured by Elmore Milling Company, Inc., Oneonta, New York."

LIBELED: 5–14–60, Dist. Vt.

CHARGE: 501(c)—when shipped, the strength of the article differed from and its quality fell below that which it purported and was represented to possess since the 22-bag lot contained less than the declared amount of arsanilic acid, and the 6-bag lot contained less than the declared amount of 3-nitro-4 hydroxyphenylarsonic acid.

The libel alleged also that another article known as "Hog Ration" was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 6–3–60. Consent—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6213. Tranquilease (cosmetic cream). (F.D.C. No. 41505. S. No. 4–382 P.)

QUANTITY: 48 individually cartoned jars at Washington, D.C.

SHIPPED: 1–20–58, from Philadelphia, Pa., by Denney & Denney, Inc.

LABEL IN PART: (Jar) "TRANQUILEASE · FRANCES DENNEY The Original Cosmetic Tranquilizer for the Skin * * * 1.8 Oz. Net."

ACCOMPANYING LABELING: Carton inserts entitled "Tranquilease The only cosmetic of its kind" and leaflets entitled "Bulletin from Frances Denney."

RESULTS OF INVESTIGATION: Analysis showed that the article was a white, perfumed oil-in-water cream emulsion containing glycerol monostearate, waxes (including lanolin and/or sterols), inorganic pigments (mostly zinc oxide and titanium dioxide), mineral oil, glycerol, and a nitrogen compound (probably an amide).

LIBELED: 4–4–58, Dist. Columbia.

CHARGE: 502(a)—when shipped, the labeling and the name of the article contained false and misleading representations that the article would tranquilize the skin and correct all abnormal skin conditions resulting from emotional upsets, tension, and fatigue.

The libel alleged also that the article was misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics.

DISPOSITION: On 5–15–58, Frances Denney and Denney & Denney, Inc., appeared as claimants and denied that the article was a drug or that it was misbranded. Thereafter, the Government and the claimants filed written interrogatories. The claimants objected in part to the Government's interrogatories for specific reasons, and a further general objection was made to all the interrogatories on the grounds of self-incrimination. On 11–14–58, the court entered the following memorandum opinion, ruling against the claimants on their self-incrimination objection, and ruling in part for the claimants and in part for the Government on the other objections (23 F.R.D. 192):

*See also Nos. 6203, 6205, 6207–6211.

TAMM, *District Judge:* "This suit is one in libel filed by the United States of America under Title 21, United States Code, Secs. 301, et seq. and prays for seizure and condemnation of a certain article of drug and cosmetic on the ground that the article was misbranded when introduced into, and while in interstate commerce, within the meaning of the Federal Food, Drug and Cosmetic Act.

"Subsequent to proper process and publication, the libellee filed its answer to the libel of information and denies that the article is a drug, denies that there was labeling, and denies that there was misbranding. It asserts that the name, 'Tranquilease,' is a coined word and has no meaning aside from the meaning given it by naming this product.

"The claimants, Frances Denney and Denney and Denney, Pennsylvania corporations, addressed interrogatories under Rule 33, Federal Rules of Civil Procedure, to the libellant and said interrogatories were answered. Libellant, United States of America, then addressed interrogatories to the claimants—said interrogatories being objected to by the claimants mainly on the ground that 'disclosure of the information requested might tend to incriminate any responsible corporate officer or agent called on to furnish information on behalf of claimants in violation of the Fifth Amendment.' Other objections are based upon irrelevancy, revelation of a trade secret without a showing of its need by the libellant and an attempt to secure the results of work performed by experts.

"Subsequently, on August 20, 1958, the claimant corporations and their president William F. Denney were named in and served with a notice of hearing preliminary to a determination whether criminal action will be undertaken. This is the factual background upon which the claimants base their objections to the interrogatories served by the libellant, United States of America. The claimants allege that if they are required to answer the interrogatories the answer will, or may possibly, serve as the basis for a criminal action, and thus they would be testifying against themselves in violation of the Fifth Amendment. The threat of a criminal action is more than a bare possibility as seen from the 'Notice of Hearing,' 'Charge Sheet,' and other papers served upon the corporations and their president.

Objection based on self-incrimination.

"All parties to this action do agree that corporations do not have the right, as do individuals, to assert the privilege against self-incrimination. The argument of the United States stems directly from this basic concept for it asserts that since corporations are the parties to this action and not individuals, the privilege against self-incrimination does not play a part in this proceeding. However, the libellees answer this contention by saying that because of the broad criminal liability imposed by the Federal Food, Drug and Cosmetic Act, whoever answers these interrogatories puts himself, personally, in a responsible relation to the corporation, and under the reasoning of the case of *United States* v. *Dotterweich*, 320 U.S. 277, tends to incriminate himself.

"In the *Dotterweich* case, *supra*, the Court through Mr. Justice Frankfurter discussed the history of the present code provision and its development from the Food and Drugs Act of 1906. The Court also pointed out that 'such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good, it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger.' (P. 281)

The Court continues:

> The Act is concerned not with the proprietory relation to a misbranded or an adulterated drug, but with its distribution. In the case of a corporation such distribution must be accomplished, and may be furthered, by persons standing in various relations to the incorporeal proprietor. (P. 283)
>
> * * *
>
> The Circuit Court of Appeals was evidently tempted to make such a devitalizing use of the guaranty provision through fear that an enforcement

> of § 301(a) as written might operate too harshly by sweeping within its condemnation any person however remotely entangled in the proscribed shipment. But that is not the way to read legislation. Literalism and evisceration are equally to be avoided. To speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty. Whether an accused shares responsibility in the business process resulting in unlawful distribution depends on the evidence produced at the trial and its submission—assuming the evidence warrants it—to the jury under appropriate guidance. The offense is committed, unless the enterprise which they are serving enjoys the immunity of a guaranty, by all who do have such a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. (p. 284)

"Thus, it is seen that regardless of conscious fraud, anyone who shares in the responsibility in the business process resulting in unlawful distribution commits an offense. This is the basis for the reasoning of the libellees. They argue that 'after a notice of hearing has been served, any one of claimant's officers or agents who undertakes to answer these interrogatories on behalf of the corporation fixes his position as one who stands in "responsible" relation to the corporation and thereby tends to incriminate himself under Dotterweich.'

"However, this Court does not believe that the holding of the *Dotterweich* case, *supra*, is to be applied as broadly as libellees contend. It is apparent from the *Dotterweich* case that one will be held criminally liable if he has a responsible share in the furtherance of the acts which the statute outlaws. However, to adopt the position contended for by the libellees is equivalent to saying that one who answers interrogatories addressed to the corporation automatically assumes a responsible relation or share in the furtherance of the outlawed transaction merely by answering interrogatories. But answering interrogatories is not what the statute outlaws. It is true that the corporation, in selecting an officer or agent to answer the interrogatories, could conceivably select one who, without being conscious of doing so, would be answering questions that would tend to incriminate himself. However, it is more rational to assume that since the corporations and their president have been advised in what manner they have allegedly violated the statute and have knowledge of all who were in a responsible relation to such violation, they also have knowledge of those who were not involved. Therefore, the libellees could select to answer the interrogatories to the best of his ability one who would not thereby be incriminated. Merely because a person is an officer or agent of the corporations does not per se mean that he automatically stands in a position of criminal liability, for the *Dotterweich* case specifically holds that a person must have a responsible share in the furtherance of the transactions which the statute outlaws.

"In the case of *Paul Harrigan & Sons, Inc.* v. *Enterprise Animal Oil Co., Inc.*, U.S.D.C., E.D. Pa. (1953, 18 Fed. Rules Serv. 33.325, Case 1), a similar situation arose. In that case, a private civil action, all of the defendants were also defendants in pending criminal proceedings. All of the officers of the corporate defendants who had knowledge of the facts and were authorized to answer interrogatories had been indicted individually. The plaintiff propounded interrogatories to each of the defendants sued in the civil action—the interrogatories seeking information and records concerning acts of the defendants which could serve as part of the proof of the criminal charges which were pending. Objections were made to the interrogatories on the ground that if the defendants were compelled to answer, they would be testifying against themselves in violation of the Fifth Amendment. As to the corporate defendants, the Court wrote:

> * * * a twofold problem is presented. First the information sought is within the knowledge of officers who have been indicted individually and secondly, all those officers who are authorized to answer interrogatories have also been indicted individually.

"The Court, in holding that the objections to the interrogatories were well founded and would be sustained, went further and wrote:

> * * * it appears to the court that the interests of justice require the application of the principle enunciated in Rule 30(b) and discovery, insofar as it relates to the indicted defendants, will be postponed until the termination of the criminal action. While this will, undoubtedly, cause inconvenience and delay to the plaintiff, protection of the defendants' constitutional rights is the more important consideration.

"In a more recent case, *United States* v. *42 Jars 'Bee Royal Capsules'*, 25 Fed. Rules Serv., 33.325, Case 1, U.S.D.C. New Jersey (1958), a different solution was reached to a problem similar in nature to the one before this Court.

"Bee Royale, Inc., a New York corporation, was the claimant of the seized goods. During the discovery proceedings, the claimant objected to interrogatories asked of it by the libellant. The objections were based on a denial of the constitutional privilege of freedom from self-incrimination. The court decided the case on the basic ground that since the privilege against self-incrimination is given only to natural persons, the corporation may not refuse to answer the interrogatories on this ground. The solution ordered by that court was as follows: (p. 557)

> True it is that the answer of this corporation to this interrogatory must be sworn to by some individual who is its 'officer or agent,' who shall furnish such information as is available to the party. F.R.C.P. 33. Of course, if any such officer or agent, who is directed by the corporation to make these answers, can establish that such answers will incriminate him, he can refuse to answer them because of his right to avail himself of the aforesaid privilege. *U.S.* v. *White*, *supra*. But if the corporation select such a person to answer these interrogatories, and, because of his pleading this privilege, these interrogatories are therefore not answered, the corporation itself will be in default, for not making the requisite discovery under the rules. It will thus be the clear *duty of the corporation to select an officer or agent for the above purpose, who will not have personally participated in anywise in any such questionable transaction*, and *who thus cannot be incriminated by such answers*. This the corporation can easily do under its broad corporate powers, using even its attorney, for instance, whose duty it would then be to 'furnish such information as is available to the party'—the sum total of the corporate information. * * * (Emphasis supplied)

> It therefore follows that since (1) this corporation can appoint some officer or agent to answer interrogatories for it who will not be personally incriminated by such answers, and since (2) the corporation itself cannot claim any privilege against self-incrimination, it has no right to plead that privilege, as an objection to answering the interrogatories here in question.

"No mention of the *Dotterweich* case, *supra*, is made in the foregoing opinion, as the libellees have pointed out in their points and authorities.

"Thus, from the foregoing cases, it seems that two courses are open to this Court:

1. Require the corporation to select an officer or agent to answer the interrogatories—that is—an agent who will not incriminate himself by any answers, or
2. Stay discovery proceedings in the libel suit until the criminal proceedings have been completed.

"This Court is of the opinion that the proper course to follow in this case is to require the corporations to appoint an officer or agent who will not be incriminated by his actions to answer the interrogatories, and the Court, accordingly, directs that this be done.

Interrogatory No. 6.

"Interrogatory No. 6 is as follows:

> What meaning do claimants intend to convey to the public by the following expressions used in the labeling:
>
> (a) Tranquilizer for the skin
> (b) Give a tranquil effect to the skin
> (c) Lull the skin

(d) Pacify the complexion
(e) Calm the skin
(f) A corrective preparation
(g) Relieve the modern problem of the skin.

"Claimants object to this interrogatory on the ground that it is irrelevant and that intended use is to be determined from the representations in the labeling. The libellant contends that this is relevant for it applies to the issue as to whether 'Tranquilease' is a drug. While the contention of the libellant is true, it is equally true—as libellees contend—that this determination should be made from the labeling itself. In all the authorities cited to this Court, this determination was made from an analysis of the labeling itself, as for example in the case of *United States* v. *46 Cartons, More or Less, Containing Fairfax Cigarettes, etc.*, 113 F. Supp. 336 (1953). Therefore, this Court concludes that the objection to Interrogatory No. 6 is well founded, and the objection will be sustained.

Interrogatory No. 8.

"Interrogatory No. 8 is as follows:

(a) What is the quantitative and qualitative formula for 'Tranquilease'?
(b) Which ingredients in 'Tranquilease' are the active ingredients?
(c) Explain the action of each active ingredient.

"Claimants object to this interrogatory on the ground that to require a disclosure would, in effect, be disclosure of a trade secret. *Moore's Federal Practice*, Sec. 26.22(3) states:

> While there is no definite privilege against discovery of trade secrets and secret processes the courts will normally hesitate to require disclosure of such matters, and Rule 30(b) provides that the court may order 'that secret processes, developments, or research need not be disclosed.' But if the information is relevant and necessary to the presentation of the case, it will be required. The court may impose special conditions to protect the party.

"A determination of a question such as this usually lies within the discretion of the Court. In the case of *V. D. Anderson Co.* v. *Helena Cotton Oil Co.*, 117 F. Supp. 932, 941, there is the following:

> With reference to the plaintiff's objections that some of the defendant interrogatories will require the disclosure of 'confidential information,' it may be said, generally speaking, that trade secrets are not privileged; while the Court has the power, under the provisions of Rule 30(b) to direct that such secrets need not be disclosed, nevertheless, 'if the information is relevant and necessary to the presentation of the case, it will be required,' and the court 'may impose special conditions to protect the party.'

"The Court in that case rejected that objection to the interrogatory.

"This Court concludes that the obvious relevancy and materiality of the interrogatory plus its necessity must outweigh the objection advanced by the libellees, and therefore, the objection to Interrogatory No. 8 is overruled.

Interrogatories Nos. 11 and 12.

"Interrogatories No. 11 and No. 12 are as follows:

11. State whether claimants have conducted any clinical tests to support the statements made in answer to questions 9 and 10 above.
   (a) If so, state the name of the person conducting the tests, and the time and place at which conducted.
   (b) Give the results of such tests.

12. Give the names of any physicians or dermatologists contacted by the claimants who support claimants' contentions concerning the effect of Tranquilease upon the skin.
   (a) State the date such physicians or dermatologists were first contacted by claimants.

"Claimants object to these interrogatories mainly on the ground that they 'represent an attempt to secure the results of work performed by experts who are generally, and particularly in Food and Drug cases, shielded from interrogation by the opposing party.' The libellant argues that the interrogatories are directed towards obtaining information concerning the work of experts who should have been employed by the claimants even before the case arose and that they are relevant. The general rule in situations such as this is perhaps best expressed by Moore in *Moore's Federal Practice*, Sec. 26.24, p. 1158, who writes:

> The court should not ordinarily permit one party to examine an expert engaged by the adverse party, or to inspect reports prepared by such experts, in the absence of a showing that the facts or the information sought are necessary for the moving party's preparation for trial and cannot be obtained by the moving party's independent investigation or research.

"Although the Government has not made an express or affirmative showing that this information is necessary for preparation for trial and cannot be obtained by its independent investigation or research, yet a main issue in the case is whether the claims made of 'Tranquilease' are false and misleading. The questions propounded by the libellant are directed to tests, if any, and experts, if any, that will support the position of the claimants on the issue of whether the claims made for the article are false or misleading. It appears from the questions themselves that they are requesting matter of such a nature that it is within the possession or knowledge of the claimants only and that the libellant can in no way obtain such information through independent investigation or research. In the case of *U.S.* v. *132 Cartons * * * Chloresium Tooth Paste*, decided March 27, 1950, U.S.D.C. for Dist. of Connecticut, Judge Hincks wrote the following:

> * * * I have come to the conclusion that to facilitate its cross-examination of claimant's witnesses and to prepare its rebuttal to claimant's defense the government is entitled to the discovery through the proposed deponents which it names of all matters not privileged. * * * Libellant insisted that the discovery was necessary not to elicit their opinions as experts but rather to ascertain the factual scope and nature of the research done so that it possibly may be in a better position to cross-examine these witnesses on trial and prepare a rebuttal to the claimant's defense. Having in mind that the field in question here is one of scientific controversy wherein without prior discovery cross-examination cannot be expected successfully to perform its historic function, and effective evidence in rebuttal, though perhaps in existence, cannot be produced forthwith upon the close of the claimant's defense, I feel that here there is sufficient showing of necessity, within the rule of *Hickman* v. *Taylor* if applicable here, to allow the discovery to proceed.

"Based upon the issues involved, the need of the Government for the desired information, the lack of other sources, and the foregoing authority, this Court hereby overrules objections to Interrogatories Nos. 11 and 12.

"Counsel will submit order."

An order was entered in accordance with the opinion and the interrogatories were answered by the claimants. Thereafter, the Government filed a motion for summary judgment. On 10–20–59, the claimants filed a motion to withdraw their claim and answer. On 10–29–59, an order was entered by the court withdrawing claimant's claim and answer and directing that the article be condemned and destroyed. On 11–16–59, the article was destroyed.

6214. Vi-San Food Supplement. (F.D.C. No. 42462. S. Nos. 36–446 M, 11–762 P, 11–769 P.)

INFORMATION FILED: 4–27–59, S. Dist. Calif., against Vi-San Nutritional Laboratories, a corporation, Burbank, Calif.

SHIPPED: Between 9–27–57 and 3–25–58, from Burbank, Calif., to Detroit, Mich.

LABEL IN PART: (Box) "VI-SAN Food Supplement THERAPEUTIC, * * * Contents 60 Red Vitamin Capsules 180 Green Mineral Tablets * * * Manufactured by the Vi-San Nutritional Laboratories, Burbank, California."

ACCOMPANYING LABELING: Phonograph records designated "Vi-San Nutritional Laboratories Your Priceless Possession" and "Vi-San Recording Prescription For Better Living"; pamphlet entitled "Record O Gram"; booklet entitled "Your Priceless Possession"; folder designated "Marketing Plan" consisting of a booklet entitled "Marketing Plan Distributor Record-Keeping System" and a small folder headed "Coffee Cup Career"; folder designated "The Atomic You" consisting of booklets entitled "The Vi-San Story" and "Why Millions of Americans"; folders entitled "For You The Very Best," "Live Lively," "Prescription for Better Living," "Mink Coats for Vi-San Minerals," "Why Feel Old?" and "A Report On The Health Of The Nation"; a box label which purported to describe the contents of the enclosed capsules and tablets; a statement on the lid of the plastic container enclosed in the box; and an insert card in the plastic container which purported to describe the composition of the capsules and tablets.

CHARGE: 502(a)—when shipped: (a) the labeling of the article contained false and misleading representations that the article was adequate and effective for the prevention and treatment of allergies; arthritis; blindness; cancer; cerebral palsy; chronic infections; colds; constipation; coronary thrombosis; deafness; dental caries; diabetes; diarrhea; disgestive problems; distorted heart rhythm; dry skin, hair, and nails; emotional instability; epilepsy; fatigue; fear complex; functional and organic disease; headache; heart trouble; infantile paralysis; insomnia; loss of manual dexterity; loss of weight; lowered body efficiency; lusterless eyes; mental confusion; mental deficiency; mental illness; multiple sclerosis; muscular dystrophy; nephrosis; neuritis; poor blood coagulation; sinus trouble; skin inflammations; sores; tuberculosis; virus infections; and weakness; (b) the labeling contained representations that the article was a necessary and required adjunct to the diet because the average American person has a serious dietary deficiency of the vitamins and minerals supplied by the article; that consumption of protein in this country is far below the optimum requirement; and that the article contributed protein to the diet, which representations were false and misleading since the average American person's diet is not deficient in vitamins and minerals, consumption of protein in this country is adequate, and the article would contribute only trivial amounts of protein to the diet; (c) the labeling contained also false and misleading representations that use of the article would be a major step toward better living; that use of the article assured nutritional health; that use of the article was never contraindicated; that practically everyone in this country is suffering from, or is in danger of suffering from, a serious dietary deficiency of vitamins and minerals due to foods being grown on depleted soils, and due to the pasteurization, storage, canning, processing, refining, shipping, freezing, and cooking of foods; that the ingredients and components: Mycozyme, papain, rice polishings, rose hips, egg shell, oyster shell, prune concentrate, sea salt trace minerals, sea lettuce, mint leaves, sulfur, citrus peel and infusion, wheat germ, chlorophyll, montmorillonite, rutin, cabbage, parsley, watercress, alfalfa, boron, and nickel, provided exceptional nutritive value of unknown mysterious character to the article; that the great majority of people would be benefited by the addition of even small quantities of essential vitamins and minerals to their usual diet; that

vitamin and mineral supplements added years to one's life; and that vitamins and minerals aided in controlling weight; that the daily use of the article was necessary for good nutritional health, a more abundant vitality, and greater energy for work or play; that the article, by supplying alfalfa extract, would be as valuable an additive to human nutrition as was alfalfa when included in the ration of animals; that the extract of alfalfa contained in the article was a valuable factor in reproduction, growth, and development and increased resistance to infection in human beings, and had mysterious nutritive value beyond that of the known nutrient substances found in alfalfa; and that anyone who did not use the article would be likely to subject himself to prolonged inadequate nutrition which would adversely affect physical appearance, eyes, hair, emotional stability, vitality, growth, development, resistance to disease, ability to learn, and ability to succeed in business, trade, and profession; that the article was superior to all other vitamin-mineral supplements and was the only such supplement that was entitled to be called "therapeutic"; (d) that the statements in the labeling "When these tiny microscopic cells are robbed of vital MICRO-NUTRIENTS (vitamins and minerals) due to a deficient diet; or are damaged by poisons, bacterial invasions, parasites, etc., they become TIRED–INEFFICIENT or SICK. Unless the cause is corrected, either by supplementing the diet (if a lack of these MICRO-NUTRIENTS is the cause), or by professional treatment (in case of injury, functional or organic disease) these cells may finally become so sick, they will DIE!" were misleading since such statements suggested that dietary deficiencies in vitamins and minerals are a major cause of cell deterioration, sickness, and death, whereas, in an overwhelming majority of cases, cell deterioration, sickness, and death are due to causes other than dietary deficiencies in vitamins and minerals; (e) the statements in the labeling "We eat refined sugars and starches; such as, pies, cakes, bread, cereals, candy etc., as though our lives depended upon them! These sugars and starches represent over 50% of our total caloric intake, and are almost totally lacking in vitamins and minerals." were false and misleading since pies, cakes, bread, and cereals are not composed solely of refined sugars and starches, and they do contain material quantities of vitamins and minerals; (f) the statements in the labeling "Today MILLIONS of people EXIST in a sort of 'twilight zone' between health and illness being neither PHYSICALLY VITAL nor actually sick, but they accept this condition as 'good health' because they are not bedridden or because they have no evident clinical manifestations of disease. These people suffer from minor complaints rather than physical disorder. They complain of 'weakness' of 'being tired,' 'irritability' or 'digestive troubles.' Constipation, headaches, colds, 'virus infections' or other minor disorders are daily companions. If you are one of the millions putting up with these aggravating tiresome symptoms, and they are not due to external, organic or functional causes, there is great new hope shining through the window of science for you!" were misleading in that they failed to reveal the fact, material in the light of such representations, that in an overwhelming majority of cases such symptoms or conditions are due to external, organic, or functional causes; (g) the labeling contained the statements: "VI-SAN contains many, many different factors to supply a most complete balanced formula. If you're an 'average person' it's very possible you have one or more deficiency symptoms due to a diet that has not been adequate in MICRO-NUTRIENTS, essential vitamins and minerals, for a prolonged period of time. On the following page you will find

a list of deficiency symptoms. Check them and you will probably quickly realize the need for a QUALITY dietary supplement. CHECK LIST OF DEFICIENCY SYMPTOMS It must be realized that while these conditions can be brought about by prolonged multi-vitamin and mineral deficiencies, they can also be due to external causes, or to organic or functional diseases not related to nutritional deficiencies. Fatigue Lethargy or weakness Lowered body efficiency Hypersensitivity to noise Distorted heart rhythm Skin spots or inflammation Dim night vision Emotional irritability Digestive Upsets Muscular weakness Mental confusion Nervousness Loss of weight Depression Dental caries Loss of muscle tone Dizziness Irritation of gums Constipation Loss of appetite Loss of manual dexterity Rough dry hair and skin Diarrhea Headache Fear complex Insomnia Neuritis Sores on corners of lips Swelling and redness of tongue Eyes sensitive to light Anemia Slow healing cuts Poor blood coagulation Multi-vitamin and multi-mineral supplementation will not, of course, remedy diseases not due to nutritional deficiencies. However, a nutritional deficiency does retard the body's ability to overcome both acute and chronic conditions," which statements were false and misleading in that they suggested that the average person with any such symptoms very possibly could obtain relief by the use of Vi-San, whereas in the overwhelming majority of cases, most such symptoms and conditions are due to external causes or to organic or functional diseases, and not to nutritional deficiencies.

PLEA: Nolo contendere.

DISPOSITION: 4–25–60. $1,500 fine.

6215. Cowlserpa (reserpine) tablets, atropine sulfate tablets, digitalis tablets, and Salamin tablets. (F.D.C. No. 42435. S. Nos. 64–348 M, 8–544 P, 8–785 P, 11–955 P.)

INFORMATION FILED: 4–30–59. Dist. Mass., against Cowley Pharmaceuticals, Inc., and Benjamin (Ben) C. Cowley, president, Auburn, Mass.

SHIPPED: Between 7–19–57 and 3–12–58, from Massachusetts to New York and Michigan.

LABEL IN PART: "1000 Tablets COWLSERPA (Brand of Reserpine) * * * Distributed and Sold Exclusively by ZIEGLER PHARMACAL CORP. BUFFALO 2, N.Y. 6531"; "45,000 Tablets ATROPINE SULFATE" [or "5000 TABLETS DIGITALIS RED" or "1000 tablets SALAMIN PAS TIMED DISINTEGRATION] * * * COWLEY PHARMACEUTICALS, INC."

CHARGE: 502(a)—the statements on the labels of the articles, namely, (*Cowlserpa tablets*) "Each tablet contains: Reserpine 0.25 mg.," (*atropine sulfate tablets*) "Each Tablet contains: Atropine Sulfate 1/300 gr.," and (*digitalis tablets*) "Digitalis * * * 1½ gr." were false and misleading since each *Cowlserpa tablet* contained less than 0.25 milligram of reserpine, each *atropine sulfate tablet* contained less than 1/300 grain of atropine sulfate, and each *digitalis tablet* contained less than 1½ grains of digitalis; and the statement on the label of the *Salamin tablets*, namely, "Each tablet contains: 0.5 gm. Para-Aminosalicylic Acid Dihydrate For a timed release over a period of 6–8 hours," was false and misleading since each *Salamin tablet* failed to release 0.5 gram of para-aminosalicylic acid in an 8-hour period.

The information alleged also that another product, namely, Metavites tablets, was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

PLEA: Guilty.

DISPOSITION: 5-23-60. Corporation—$500 fine; Cowley—$1,000 fine, $500 of which was suspended, and probation for 1 year.

6216. Victorvita Food Supplement. (F.D.C. No. 44555. S. No. 39-001 R.)

QUANTITY: 100 180-tablet boxes at St. Louis, Mo.

SHIPPED: 9-3-59, from Sepulveda, Calif., by Victor Vitamin Co.

LABEL IN PART: (Box) "Victorvita The Food Supplement for the feel of Youth Victor's Multi Vitamins and Minerals * * * composed largely from extracts and concentrates of organic substances, such as yeast, liver, alfalfa, buckwheat, parsley, watercress, oranges, lemons, bone meal, kelp, and many, many, others * * * further fortified with added amounts of the highest quality pure crystalline vitamins and various minerals so necessary to the human diet * * * This package contains 60 vitamin tablets and 120 mineral tablets. Packaged in 60 individual airtight packets. Each packet contains one vitamin (brown) and two mineral (red) tablets. Victor Vitamin Co., Palms Station Box 34804 Los Angeles 34, California."

ACCOMPANYING LABELING: White leaflets entitled "Have a Brighter Future . . . Victorvita The Food Supplement for the Feel of Youth"; pink leaflets entitled "Have a Brighter Future"; and a letter dated 7-20-59, from the Victor Vitamin Co. with a 13-page enclosure.

LIBELED: 5-3-60, E. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of nervous tension; irritability; fatigue; tiredness; digestive discomforts and difficulties; premature aging; loss of appetite; lowered resistance to infection of mucous membranes of the eyes, nose, mouth, and throat; night blindness; anemia; defective teeth; muscle weakness; tooth decay; bone disorders; rickets; poor bone and tooth development in children; neuritis; loss of muscle tone; mental depression; vague aches and pains; constipation; dryness of the hair and skin; reddening of the lips; inflammation of the mouth and soreness about the angles of the mouth; minor skin eruptions; insomnia; paleness; difficulty in breathing; growth failure in children; dizziness; headaches; unpleasant body odors and bad breath; lack of energy; obesity; goiter; and that the article would produce a brighter future; feel of youth; health; pep; attractiveness; better thinking; regular bowel movements; build blood; and clot blood.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 6-6-60. Default—destruction.

6217. Abundavita vitamin tablets, Abundavita mineral tablets, and Abundagreen. (F.D.C. No. 44197. S. Nos. 50-087/8 P, 50-622 P, 71-058/9 P.)

QUANTITY: 14 cases, each containing 12 btls., of *Abundavita mineral tablets;* 6 cases, each containing 24 1-lb. bags of *Abundagreen;* and 104 btls. of *Abundavita vitamin tablets* at Cincinnati, Ohio, in possession of Bruce Helvie.

SHIPPED: On various dates during the latter part of 1959 and in January 1960, from Long Beach, Calif., by Abundavita Corp. of America.

LABEL IN PART: (Btl.) "Abundavita Food Supplement Mineral Tablets Natural or Organic * * * In an exclusive *Hunza Base (*Specially Prepared Selected Grasses Grown on the Hunza Farm in Natural Occurring Glacial Silt) * * *

Formulated for and Distributed by Abundavita Corporation of America * * * Long Beach, California"; (bag) "All Purpose Abundagreen Natural Organic From Specially Prepared Selected Grasses Grown on the Hunza Farm in Natural Occurring Glacial Silt * * * Abundavita Corporation of America * * * Long Beach 5, Calif."; and (btl.) "Abundavita Food Supplement Vitamin Tablets * * * Two tablets daily will supply * * * In an exclusive *Hunza Base (*Specially Prepared Selected Grasses Grown on the Hunza Farm in Natural Occurring Glacial Silt) * * * Abundavita Corporation of America * * * Long Beach 5, Calif."

ACCOMPANYING LABELING: Booklet entitled "A New Way of Life For You and Your Family"; leaflets entitled "A New Way of Life," "The Hunza Farm," "Abundavita Food Supplement," and "Abundavita Beverage"; window sign entitled "Don't Grow Old Too Young! Eat Hunza Grass and Abundavita"; and placards entitled "How Do You Feel . . . " and "Most Economical * * * Abundavita and Hunza."

RESULTS OF INVESTIGATION: The booklet and leaflets were received by the dealer from or on behalf of the Abundavita Corp. of America and the window sign and placards were prepared locally by or on behalf of the dealer.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective to produce longevity and superb, perfect, and radiant health, happiness, hardihood, vigor, and good eyesight; resulted in men being active and sexually potent until age 100; resulted in women being beautiful and youthful in their 70's and 80's; prevented chronic illness; produced muscular fitness; conditioned the intestines and aided bowel movements; appeased the appetite and controlled weight; deodorized the body; cleaned and lubricated the intestinal tract, including the colon; allayed putrefaction in the colon; stimulated action of the colon; that the articles were adequate and effective for the treatment and prevention of headaches, irritability, nervousness, and mental depression; fatigue; dizziness; vague aches and pains; neuritis; insomnia; loss of muscle tone; weakness; loss of weight; indigestion; digestive upsets; loss of appetite; diarrhea; constipation; inflammation of the mouth; sores about the angles of the mouth; reddening of the lips; swelling and redness of the tongue; and dryness of hair or skin.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 5–25–60. Consent—claimed by Bruce Helvie, and ordered released under bond for relabeling.

6218. **Various vitamin preparations.** (F.D.C. No. 44190. S. Nos. 99–261/77 P.)

QUANTITY: 29,951,258 vitamin capsules consisting of *vitamin A capsules, vitamins A & D capsules, vitamin E capsules, wheat germ oil capsules, Adavite capsules, Minaquin capsules, Quin-Kaps capsules, Theracrest capsules, Theravim capsules,* and *Zel-Kaps capsules,* and 15 5-gal. drums and 525 16-fluid oz. btls. of *wheat germ oil* and *Neo-Vi drops,* at New York, N.Y., in possession of Hudson Vitamin Products, Inc.

SHIPPED: Prior to 1–22–60, from outside the State of New York.

LABEL IN PART: "Hudson Vitamin 'A' 100 [or "250"] capsules Natural [or "Synthetic" or "Water Soluble"] 25,000 [or "50,000"] U.S.P. Units Hudson Vitamin Products, Inc.," "Hudson A & D Vitamins 100 [or "250"] capsules," "Hudson E-Kaps 100 [or "250"] capsules," "Hudson Wheat Germ Oil 100

[or "250"] Capsules 3 minims each [or "4 fluid ounces"], "Hudson Adavite 100 [or "250"] capsules Fortified Therapeutic Vitamins," "Hudson Neo-Vi 60 cc. drops New and improved water-dispersible multivitamin drops with Vitamin B–12," "Hudson Minaquin 100 [or "250"] capsules Vitamins with Minerals," "Hudson Quin-Kaps 100 [or "250"] capsules Improved Poly-vitamins," "Hudson Theracrest 100 [or "50" or "250"] capsules Fortified Therapeutic Polyvitamins," "Hudson Theravim 100 [or "250"] capsules Therapeutic Vitamins Minerals Increased Potency," "Hudson Zel-Kaps 100 [or "250"] capsules High Potency Multiple Vitamins."

ACCOMPANYING LABELING: Booklets entitled "Hudson Vitamin Catalog January, 1960."

RESULTS OF INVESTIGATION: The booklets were printed for Hudson Vitamin Products, Inc., for promotional purposes and to explain the use of the articles.

LIBELED: 1–22–60, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the articles was false and misleading as follows:

(a) *Vitamin A Natural, Vitamin A Synthetic, Vitamin A Water Soluble*—the labeling of the articles contained representations that infections, low resistance to infections, including infection by the common cold, ophthalmic disorders, retarded growth, low vitality, loss of vigor, and night blindness are commonly and usually caused by deficiencies of vitamin A in the diet; that use of the articles would correct and prevent such conditions; and that the natural sources of vitamin A are limited to green vegetables, tomatoes, eggs, and butter, which representations were false and misleading since the conditions named are rarely, if ever, caused by a deficiency of vitamin A in the diet; use of the articles would not prevent or correct such conditions; and vitamin A is readily available in many foods which comprise the normal diet and not only in those foods listed as supplying the natural sources of vitamin A;

(b) *Vitamins A & D capsules*—the labeling of the article contained representations that infections, low resistance to infections, ophthalmic disorders, retarded growth, low vitality, sterility, loss of vigor, night blindness, tooth decay, bone deformities, and muscular weakness are usually caused by a deficiency of vitamins A and D in the diet; that use of the article would correct and prevent such conditions; and that the natural sources of vitamin A are limited to green vegetables, tomatoes, eggs, and butter and the natural sources of vitamin D are limited to cod liver oil, sunlight, eggs, and milk, which representations were false and misleading since such conditions are rarely, if ever, caused by deficiencies of vitamins A and D in the diet; use of the articles would not prevent or correct such conditions; and vitamins A and D are readily available in many foods which comprise the normal diet and not only in those foods listed in the labeling as supplying the natural sources of vitamins A and D;

(c) *E-Kaps (Vitamin E) Natural, wheat germ oil capsules and wheat germ oil liquid, Neo-Vi drops, Theracrest capsules, Theravim capsules*—the labeling of the articles contained representations that the articles were adequate and effective for the treatment and prevention of sterility, muscular dystrophy, failure of reproduction, abortion, heart conditions and abnormal muscular conditions and to promote muscular mobility; and that the natural sources of vitamin E are limited to wheat germ, whole cereals, and whole wheat, which representations were false and misleading since the articles were not adequate and effective for the treatment and prevention of such conditions or to promote

muscular mobility; and vitamin E is readily available in many articles of the ordinary diet and not only in the foods listed in the labeling, and it is unnecessary to supplement the diet to obtain an adequate amount of vitamin E;

(d) *Adavite capsules, Neo-Vi drops, Minaquin capsules, Quin-Kaps capsules Theracrest capsules, Theravim capsules,* and *Zel-Caps capsules*—the labeling of the articles represented that infections, low resistance to infection, ophthalmic disorders, retarded growth, low vitality, sterility, loss of vigor, night blindness, poor appetite or loss of appetite, neuritis, poor digestion, digestive disturbances, intestinal disturbances, fatigue, depression, depressed bodily activity, abnormal cell growth and development, nervous disorders and disturbances, disturbances of growth, skin disorders, anemias, tooth decay, hemorrhage, muscular weakness, and bone deformities are commonly and usually caused by deficiencies in the diet of vitamins A, B_1, B_2, niacinamide, B_6, B_{12}, C, and D and that use of the articles would correct and prevent such conditions; and that the natural sources of the named vitamins were limited to (A) green vegetables, eggs, tomatoes and butter, (B_1) yeast, wheat germ, and milk, (B_2) yeast, milk and eggs, (niacinamide) green vegetables, beans, yeast, (B_6) eggs, cabbage, cantaloupe, (B_{12}) liver (beef), (C) lemons, oranges, tomatoes, and grapefruit, (D) cod liver oil, sunlight, eggs and milk, which representations were false and misleading since such conditions are rarely, if ever, caused by a deficiency of these named vitamins; use of the articles would not correct or prevent such conditions; and the named vitamins are readily available in many foods which comprise the normal diet, and not only in those foods listed in the labeling as supplying the natural sources of such vitamins.

Neo-Vi drops—in addition, the labeling of the article represented that adequate and proper nutrition could be obtained by children only by such vitamin-supplementation as provided by *Neo-Vi drops* formula; and that such supplementation would balance an otherwise unregulated or improper diet for children, which representation was false and misleading since adequate nutrition for children can be easily obtained without such a supplement as *Neo-Vi drops*, and the addition of such a supplement alone does not insure a balanced diet, or proper nutrition of children.

Theracrest capsules—in addition, the labeling of the article represented that the average adult in this country is suffering from vitamin deficiencies and poor health and that the article would promote good health and provide sparkle and vigor to daily living, which representation was false and misleading since it was contrary to fact.

Theravim capsules—in addition, the labeling of the article represented and suggested that the average adult in this country is likely to be suffering from a vitamin and mineral deficiency; that the article would improve body tone and provide pep and zest to the average adult; and that a restricted diet would result in the absence of vitamins from such a diet, which representations were false and misleading since they were contrary to fact.

DISPOSITION: 1–28–60. Consent—claimed by Hudson Vitamin Products, Inc., and relabeled.

6219. **Vitamin tablets.** (F.D.C. No. 44363. S. Nos. 76–778/9 P.)

QUANTITY: 36 ctns., each containing 12,500 tablets and an undetermined number of pliofilm bags of vitamin tablets at Seattle, Wash., in possession of Howe & Co., and 359 boxes each containing one pliofilm bag of *Belle Teinte tablets* at Seattle, Wash., in possession of Sulé, Inc.

SHIPPED: Between 8–14–59 and 12–30–59, from Berkeley, Calif.

LABEL IN PART: (Ctn.) "Howe's Special Formula Tablets S.C. Yellow S–121 Each Oval Tablet Contains: %MDR Vitamin A Acetate 30,000 USP Units 750% Vitamin D (Irrad. Ergos.) 750 USP Units 187% Vitamin E 2.5 Int'l. Units * * * Dl-Methionine 20 mg. * * * Inositol 10 mg. * * * L-Lysine Monohydrochloride 10 mg. * * * Nicotinamide 20 mg. * * * Vitamin B_{12} Activity (as Cobalamin Conc.) 2.5 mcg.; (box and bag) "Belle Teinte (Teen) a daily vitamin & Amino Acid dietary supplement indicated where a deficiency of the following vitamin ingredients is present: Each tablet contains: * * * Dosage * * * Sulé, Inc. 1819 Eighth Avenue, Seattle 1, Wash. 100 tablets."

ACCOMPANYING LABELING: Empty pliofilm bags bearing the above "Belle Teinte" labels and leaflets entitled "A new break-through in beauty Belle Teinte."

RESULTS OF INVESTIGATION: The tablets in possession of Howe & Co. had been shipped in bulk cartons from Berkeley, Calif., for repackaging into pliofilm bags, relabeling, and delivery to Sulé, Inc. The pliofilm bags were furnished by Sulé, Inc. The tablets in possession of Sulé, Inc., had been shipped in bulk cartons as described above, repackaged by Howe & Co. into pliofilm bags, and further packaged by Sulé, Inc., into boxes.

LIBELED: 3–3–60, W. Dist. Wash.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective in the prevention and treatment of skin conditions, wrinkles, blemishes, and dry skin; and that it would produce complexion beauty, keep the skin smooth and soft, and produce good health and glowing vitality.

DISPOSITION: 3–24–60. Consent—claimed by Sulé, Inc., of Seattle, Wash., and released under bond for relabeling.

6220. Vitamin and mineral tablets. (F.D.C. No. 44416. S. Nos. 43–261 R, 77–565 R.)

QUANTITY: 35 90-tablet btls. of *Royal Guard minerals*, 60 270-tablet btls. of *Royal Command Vitamin-Mineral Food Supplement*, and 798 boxes, each containing 90 vitamin and 90 mineral tablets, of *Royal Guard Vitamin-Mineral Food Supplement*, at Spokane, Wash., in possession of Royal Guard Supplements, Inc.

SHIPPED: Sometime after 1–5–60, from Portland, Oreg., and Los Angeles, Calif.

ACCOMPANYING LABELING: Leaflets entitled "Royal Guard A New Wonderful Discovery."

LIBELED: 4–1–60, E. Dist. Wash.

CHARGE: 502(a)—the labeling accompanying the articles, while held for sale, contained false and misleading representations that the articles contained "beauty" vitamins which were capable of producing a lasting, lovely skin and complexion; the "sunshine" vitamin for manufacturing hormones in the glands; the "intelligence" vitamin (glutamic acid HCl) to quiet nerves, aid digestion, etc.; the "longevity" vitamins to ward off premature aging in feeling and appearance; the "heart" vitamin, vitamin E, to keep the heart young; lipotropic factors to help one handle fats and ward off atherosclerosis and thrombosis, the "great killer"; enzymes and essential amino acids to help turn food into proteins, energy, and rugged endurance, plus "ample amounts of the wonder-working minerals that are just as important as vitamins"; that the articles

contained vitamins and minerals which were capable of preventing and treating mental and emotional strain and stress; that they were adequate and effective in the prevention and treatment of tiredness; irritability; constipation; headaches; arthritis; bursitis; ulcers; colds; premature aging; and many, many other deficiency and degenerative diseases; that they were the finest health builder; that the article labeled in part "Royal Command" had 35 vitamins, minerals, and other nutrients to give better health; that the article labeled in part "Royal Guard Minerals" would quiet the nerves, ease one's pains, make strong bones and teeth, and give peaceful, restful sleep, and that the articles (all lots) were effective for the relief of all kinds of arthritis, ulcers, colitis, cramps, nerves, etc., including abdominal and muscle cramps for growing girls or women in menopause, and leg and feet cramps in boys and men.

DISPOSITION: 4–12–60. Consent—claimed by Royal Guard Supplements, Inc. The leaflets were destroyed and the articles were released to the claimant to be brought into compliance with the law.

6221. Vitamin and mineral preparations. (F.D.C. No. 44428. S. Nos. 35–241/70 R.)

QUANTITY: 204,002 various size bottles of vitamin and mineral preparations, at New York, N.Y., in possession of Foods Plus, Inc. Such preparations consisted of the following: *Vitamin A* [*Formulas 117 and 119* (*Natural*), *Formulas 142 and 143* (*Palmitate*) *and Formulas 342 and 343* (*Fat Free*)], *Vitamin A & D capsules* [*Formula 121*], *Vitamin* B_1 *tablets* [*Formulas 101 and 135*], *Vitamin* B_6 *tablets* [*Formulas 109 and 139*], *Vitamin* B_{12} *tablets* [*Formulas 134, 234 and 334*], *Vitamin E capsules* [*Formulas 125 and 126* (*Natural*) *and 325, 326 and 327* (*Fat Free*)], *wheat germ oil capsules* [*Formula 113*], *calcium pantothenate tablets* [*Formula 141*], *Basic Therapeutic Formula* [*Formula 100*], *Super Potency Vitamin Formula* [*Formula 102*], *Multi-Vitamin Formula* [*Formula 118*], *Super-Vitamin B Complex* [*Formula 152*], *Extra High Potency Formula* [*Formula 156*], *All-in-One Vitamin and Mineral capsules* [*Formula 178*], *Previtalin* [*Formula 199*], *Multiple Minerals* [*Formula 104*], and *Lecithin capsules* [*Formula 129*].

SHIPPED: Between May 1959 and April 1960, from outside the State of New York.

ACCOMPANYING LABELING: Booklets entitled "Spring 1960–Vitamin Catalog Foods Plus, Inc.," "Victor the Vitamin," "Better Health for America," "How Vitamins have helped man since the Dawn of History," and "What is Different about these Vitamins."

RESULTS OF INVESTIGATION: The booklets were printed on behalf of Food Plus, Inc., for promotional purposes and explained the use of the preparations.

LIBELED: 4–21–60, S. Dist. N.Y.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the articles was false and misleading as follows:

(a) *Vitamin A* [*Formulas 117 and 119* (*Natural*), *Formulas 142 and 143* (*Palmitate*) *and Formulas 342 and 343* (*Fat Free*)]—the labeling contained representations that infection, night blindness, lowered resistance to infection of mucous membranes of the throat, mouth, nose, and eyes, are usually caused by deficiencies of vitamin A in the diet, and that use of the articles would correct and prevent such conditions and be helpful for "resistance to illness," which representations were false and misleading since such conditions are rarely, if ever, caused by a deficiency of vitamin A in the diet, and use of the

articles would not prevent or correct such conditions, nor be helpful in raising resistance to illness;

(b) *Vitamin A & D capsules* [*Formula 121*]—the labeling contained the false and misleading representations relating to vitamin A described above, and, in addition, contained representations that poor bone and tooth development in children, muscle weakness, bone disorders, and tooth decay are usually and frequently caused by deficiencies of vitamin D in the diet, and that use of the article would correct and prevent such conditions, which representations were false and misleading since such conditions are rarely, if ever, caused by a deficiency of vitamin D in the diet, and use of the article would not prevent or correct such conditions;

(c) *Vitamin B_1 tablets* [*Formulas 101 and 135*]—the labeling contained representations that loss of appetite and muscle tone, vague aches and pains, nervousness, digestive upsets, mental depression, and constipation, are usually and frequently caused by deficiencies of vitamin B_1 in the diet, that the use of the article containing vitamin B_1 would correct and prevent such conditions, and "aid nerves, heart, and muscles," which representations were false and misleading since such conditions are rarely, if ever, caused by a deficiency of vitamin B_1 in the diet, and use of the article containing vitamin B_1 would not prevent or correct such conditions, nor aid nerves, heart, and muscles;

(d) *Vitamin B_6 tablets* [*Formulas 109 and 139*]—the labeling contained representations that nervous disorders, skin eruptions, insomnia, and irritability, are usually and frequently caused by deficiencies of vitamin B_6 in the diet, that the use of the article containing vitamin B_6, would correct and prevent such conditions, and be helpful in causing nerves, skin, and muscles to be healthy, and aid in resistance to disease through antibody production, which representations were false and misleading since such conditions are rarely, if ever, caused by a deficiency of vitamin B_6 in the diet, and use of the article containing vitamin B_6 would not prevent or correct such conditions, and would not aid in resistance to disease through antibody production.

(e) *Vitamin B_{12} tablets* [*Formulas 134, 234, and 334*]—the labeling contained representations that fatigue, chills and paleness, difficult breathing, nutritional anemia, lack of energy, and growth failure in children, are usually and frequently caused by deficiencies of vitamin B_{12} in the diet, and that use of the article containing vitamin B_{12} would correct and prevent such conditions, which representations were false and misleading since such conditions are rarely, if ever, caused by a deficiency of vitamin B_{12} in the diet, and use of the article containing vitamin B_{12} would not prevent or correct such conditions;

(f) *Vitamin E capsules* [*Formulas 125 and 126 (Natural) and 325, 326 and 327 (Fat Free)*], and *wheat germ oil capsules* [*Formula 113*]—the labeling contained representations that sterility, failure of pregnancy, menopausal, muscular, and nervous disorders, and muscular pain, are usually and frequently caused by deficiencies of vitamin E in the diet, and that use of the articles containing vitamin E would correct and prevent such conditions, which representations were false and misleading since such conditions are not caused by a deficiency of vitamin E in the diet, and use of the articles would not prevent or correct such conditions, and the statement on the labels (vitamin E capsules) "When a deficiency of Vitamin E exists" was false and misleading in that such statement represented and suggested that there may be need for dietary supplementation with vitamin E, which statement is contrary to fact;

(g) *Calcium pantothenate tablets* [*Formula 141*]—the labeling contained representations that stress and strain, polyneuritis, burning feet, and graying

of hair, are usually and frequently caused by deficiencies of calcium pantothenate in the diet, and that use of the article containing calcium panthotenate would correct and prevent such conditions, which representations were false and misleading since such conditions are rarely, if ever, caused by a deficiency of calcium pantothenate in the diet, and use of the article would not prevent or correct such conditions;

(h) *Basic Therapeutic Formula* [*Formula 100*]; *Super Potency Vitamin Formula* [*Formula 102*]; *Multi-Vitamin Formula* [*Formula 118*]; *Super-Vitamin B Complex* [*Formula 152*]; *Extra High Potency Formula* [*Formula 156*]; *All-in-One Vitamin and Mineral Capsules* [*Formula 178*]; and *Previtalin* [*Formula 199*]—the labeling contained representations that relief of tension, lack of pep and energy, nervousness, lowered resistance, extreme pressures, vigor, premature aging, loss of appetite and muscle tone, vague aches and pains, digestive upsets, mental depression, constipation, nervous disorders, skin eruptions, insomnia, irritability, fatigue, chills and paleness, difficult breathing, nutritional anemia, anemia, diseased gums, defective teeth, bones, and blood vessels, poor appetite, stress and strain, polyneuritis, burning feet, graying of hair, indigestion, general body weakness, and hardening of the arteries, are usually and frequently caused by deficiencies in the diet, of the vitamins stated in the labeling of the articles and that the use of the articles would correct and prevent such conditions; that they would aid nerves, heart, and muscles and be helpful in causing nerves, skin, and muscles to be healthy, and aid in resistance to disease through antibody production; which representations were false and misleading since such conditions are rarely, if ever, caused by deficiencies of the named ingredients in the diet, and the use of the articles would not aid nerves, heart, and muscles, or be helpful in causing nerves, skin, and muscles to be healthy, or aid in resistance to disease through the production of antibodies;

(i) *Basic Therapeutic Formula* [*Formula 100*]; *Super Potency Vitamin Formula* [*Formula 102*]; *Multi-Vitamin Formula* [*Formula 118*]; *All-in-One Vitamin and Mineral capsules* [*Formula 178*]; and *Previtalin* [*Formula 199*]—the labeling contained representations that infection, night blindness, lowered resistance to infection of mucous membranes of the throat, mouth, nose, and eyes, poor bone and tooth development in children, muscle weakness, bone disorders, tooth decay, sterility, failure of pregnancy, menopausal and muscular disorders, and muscular pain, are usually and frequently caused by deficiencies of vitamins A, D, or E in the diet, that use of the articles would correct and prevent such conditions, which representations were false and misleading since such conditions are rarely, if ever, caused by deficiencies of vitamins A, D, or E in the diet, and use of the articles would not prevent or correct such conditions;

(j) *Multiple Minerals* [*Formula 104*] and *Previtalin* [*Formula 199*]—the labeling contained representations that the articles would relieve tensions, stress and strain, nervousness, irritability, extreme pressures, fatigue, insomnia, mental depression, and would prevent premature aging, provide higher resistance to illnesses, more pep and energy, and a brighter outlook on life; that the articles when taken with vitamins increase the outlook on life; that the articles when taken with vitamins increase the effectiveness of the vitamins for the stated purposes; that the average adult in this country is likely to be suffering from a mineral deficiency; and that supplementation of the diet with the articles is essential to life and health, which representations were false and misleading since they were contrary to fact;

(k) *Lecithin capsules* [*Formula 129*]—the labeling contained representations that lecithin is a valuable addition to the diet, that by providing phospholipids to the body it was an important dietary factor because phospholipids are present in all body tissues; that lecithin, when used to supplement the diet, performs the function of aiding in the utilization and transportation of fat, preventing and removing fatty deposits, solubilizing fat, preventing and eliminating the cholesterol deposits of atherosclerosis, bringing about the proper metabolism of fats, controlling hypercholesteremia, aiding fat digestion, and making the aged feel years younger, which representations were false and misleading since they were contrary to fact;

(l) All articles except *Lecithin capsules* [*Formula 129*]—the labeling contained statements which, in the setting in which they were presented, represented and suggested:

(i) That practically everyone in this country is suffering from, or is in danger of suffering from, a serious dietary deficiency of vitamins and minerals due to foods being grown on depleted soils, and due to storage, processing, refining, shipping, and cooking of foods, which statements and representations were false and misleading since they are contrary to fact; and

(ii) That Foods Plus, Inc., was the manufacturer of the vitamin and mineral products which they offered for sale, which representations and suggestions were false and misleading since they were contrary to fact.

DISPOSITION: 5–3–60. Consent—claimed by Foods Plus, Inc., New York, N.Y., and relabeled.

6222. **Vitamin and mineral capsules.** (F.D.C. No. 44434. S. Nos. 6–761 R, 6–765 R.)

QUANTITY: 269 100-capsule btls. at Boston, Mass., in possession of Argentina Rocca Vitamin Co., Div. of NERL, Inc.

SHIPPED: 1–19–60 and 3–9–60, from Newark, N.J.

LABEL IN PART: (Btl.) "Argentina Rocca's Special Super Formula of Vitamins and Minerals 10707 Argentina Rocca Vitamin Co., Boston 15, Mass."

ACCOMPANYING LABELING: Undated form letters in the Spanish language addressed to "Muy amigo mio"; undated form letters in the English language beginning with the words "Dear Friend: Thank you," and "Dear Friend: I have not heard"; and booklets entitled "Argentina Rocca's Personal Exercises for keeping fit!"

RESULTS OF INVESTIGATION: The accompanying labeling was shipped from New York, N.Y., to Boston, Mass., on the order of Argentina Rocca Vitamin Co.

LIBELED: 4–15–60, Dist. Mass.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tenseness; irritability; fatigue; nervousness; low resistance; premature aging; infection of mucous membranes of the eyes, nose, mouth, and throat; night blindness; neuritis; loss of muscle tone; digestive upsets; vague aches and pains; mental depression; constipation; dryness of the hair and scalp; inflammation of the mouth and soreness at the corners of the mouth; skin eruptions; nervous disorders; insomnia; anemia with symptoms of tiredness, paleness, poor appetite, lack of energy, and difficulty in breathing; anemia; defective teeth; local hemorrhages of the gums and membranes of the nose and mouth;

muscle weakness; tooth decay; bone disorders; rickets and poor bone and tooth development in children; muscular pain; sterility; failure of pregnancy; muscular and nervous disorders; improper blood clotting; dizziness; indigestion; headaches; burning feet; polyneuritis; conditions resulting from stress; improper functioning of adrenal glands; porous and brittle bones; and poor resistance to colds and other common illnesses; and, in addition, the picture of the athlete, Argentina Rocca; the name of the article; and statements in the aforesaid labeling represented that the consumers of the article would develop a strong, athletic physique similar to that of Argentina Rocca, which representation was false and misleading.

DISPOSITION: 6–13–60. Default—destruction.

6223. Vitamin capsules and vitamin-mineral tablets and capsules. (F.D.C. No. 44414. S. Nos. 23–001/3 R.)

QUANTITY: 4 100-capsule btls. of *Geriatric Formula Plus B_{12}*; 4 100-tablet btls. of *Therapeutic M Vitamin-Mineral Formula;* and 53 250-capsule and 21 100-capsule btls. of *Atkins Daily Ration Multiple Vitamins* at Kansas City, Mo.

SHIPPED: 1–11–60, from Allegan, Mich., by L. Perrigo Co.

LABEL IN PART: (Btl.) "Atkins Geriatric Formula Plus B–12 To Promote Health and Vitality When Vitamins and Minerals are Indicated. Each Capsula Contains: 15 Vitamins 11 Minerals Plus Rutin-Betaine Geriatric formula provides nutritional help often required to overcome that tired feeling when Vitamins and Minerals are required. * * * Frederick Atkins, Inc., New York—Distributors"; "Atkins Therapeutic M Vitamin-Mineral Formula With Vitamin B_{12} For treatment of deficiencies of essential Vitamins and Minerals * * * Therapeutic-M provides nutritional help in therapeutic dosage where vitamins and minerals are indicated. * * * Frederick Atkins, Inc., New York—Distributors"; and (btl.) "Atkins Daily Ration Multiple Vitamins Each Capsule Supplies Full Daily Requirement of All Essential Vitamins * * * Frederick Atkins, Inc., New York—Distributors."

ACCOMPANYING LABELING: Booklets entitled "Which Vitamins For Whom When" and advertising mat entitled "Health Vitamins Beauty."

RESULTS OF INVESTIGATION: The dealer had received the booklet and advertising mat from Frederick Atkins, Inc., through whom the articles were purchased.

LIBELED: 4–5–60, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the name of the *"Geriatric Formula Plus B–12"* and its labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of tiredness; premature aging; energy failure; appetite loss; arthritis; constipation; soft, easily bleeding gums; gingivitis; neuritic pains; skin disorders; dry, scaly, and aging skin; colds; infections; insomnia; digestive upsets; and mental depression; and that the article would effect normal and efficient activity of the intestinal tract; produce a healthy state of the blood vessels and proper disposal of fats; maintain youthful vigor and resistance; supply pep and vigor; produce glowing beauty, energy, and activity; and that the use of vitamin B_{12} capsules in 10 and 25 microgram potencies would stop pernicious anemia;

502(a)—the labeling of the *"Atkins Daily Ration Multiple Vitamins"* contained false and misleading representations that the article was an adequate and effective treatment for colds; infections; for sturdy, consistent growth of youngsters; to maintain health; for bone and muscle development; to build

resistance against disease; develop alertness in children; and to produce glowing beauty;

502(a)—the labeling of the "*Atkins Therapeutic M. Vitamin-Mineral Formula*" contained false and misleading representations that the article was an adequate and effective treatment for premature aging; energy failure; tiredness; anemia; rundown conditions; appetite loss; colds; constipation; constant fatigue; soft, easily bleeding gums; gingivitis; hay fever; skin disorders; dry, scaly, or aging skin; nervous irritability; susceptibility to infections; and that the article would extend the prime of life well past retirement; furnish renewed energy, glowing beauty and general, vigorous health; restore a normal and efficient activity of the intestinal tract; and develop resistance to stress and maintain body resistance.

The libel alleged also that the "*Atkins Daily Ration Multiple Vitamins*" was misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 5–23–60. Default—the articles were delivered to a charitable institution and the advertising mats and booklets were delivered to the Food and Drug Administration.

6224. Vitamin E capsules. (F.D.C. No. 44535. S. No. 91–507 P.)

QUANTITY: 62 100-capsule btls. at Denver, Colo.

SHIPPED: Between 8–28–59 and 4–7–60, from New York, N.Y., by Approved Formulas, Inc.

LABEL IN PART: (Btl.) "Vitamin E * * * 30 [or "100" or "200"] International Units * * * Endorsed and Recommended By Gayelord Hauser Manufactured for Approved Formulas, Inc., New York * * * Each capsule contains d-alpha tocopheryl succinate (from vegetable oils) biologically equivalent to 30 International Units of Vitamin E. * * * Directions: One or two capsules daily as a dietary supplement."

LIBELED: 4–29–60, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for sterility and as an aid in reproduction; and that it was essential for healthy, germinal tissues.

DISPOSITION: 6–22–60. Default—6 bottles were delivered to the Food and Drug Administration and the remainder was destroyed.

6225. Lecithin granules. (F.D.C. No. 44252. S. No. 53–491 P.)

QUANTITY: 2 200-lb. drums and 80 11-oz. ctns. at Los Angeles, Calif., in possession of Glo-Vita Corp.

SHIPPED: Between 9–29–59 and 12–10–59, from Chicago, Ill.

LABEL IN PART: (Ctn.) "Big 'B' Pure Lecithin Granules Big 'B' Pure Lecithin is a natural, pleasant tasting food product extracted from soybeans * * * Two tbsp. of Big 'B' Pure Lecithin supply over 500 mg. each of Choline and Inositol and 450 mg. Phosphorus, 60% of the minimum daily requirement. Also contains poly-unsaturated fats (linoleic and linolenic). * * * Big 'B' Health Foods, 600 Whittier Blvd. Los Angeles 22, Cal. * * * The Billion Dollar Meal."

ACCOMPANYING LABELING: A number of loose carton labels.

RESULTS OF INVESTIGATION: The article was shipped in bulk drums as described above and after receipt by the dealer a portion of the article was repacked into the above-mentioned cartons.

Analysis showed that the article contained approximately 80 percent of the declared amount of phosphorus.

LIBELED: 2–26–60, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the carton label contained false and misleading representations that the article was adequate and effective to digest and regulate dietary fats; regulate and lower the cholesterol level of the blood; improve the functioning of the heart and the blood circulatory system; prevent heart disease and atherosclerosis; supply maximum biological benefit to the brain, nerve tissues, blood plasma, and cells of the body; and that a greater need for lecithin by persons over 35 would be satisfied by consuming the article.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 4–8–60. Consent—claimed by Bliss Vitamin Supply, Los Angeles, Calif., and relabeled.

6226. Lecithin granules. (F.D.C. No. 44429. S. No. 32–787 R.)

QUANTITY: 216 8-oz. btls. and 96 16-oz. btls. at New York, N.Y.

SHIPPED: 3–14–60 and 4–1–60, from Chicago, Ill., by Central Soya Co., Inc.

LABEL IN PART: (Btl.) "RG Lecithin * * * granules * * * a dietary source of choline, inositol and phosphorus. One tablespoonful provides 250 mg. of choline, 250 mg. of inositol and 225 mg. or 30% of the minimum adult daily requirement of phosphorus. * * * A natural food product extracted from soybeans, RG Lecithin contains both linoleic and linolenic acids, which are known as polyunsaturated fatty acids * * * Directions * * * Mfd. by and packed for Central Soya Company, Inc., Chemurgy Division, 1825 N. Laramie Ave., Chicago 39, Ill."

LIBELED: 4–21–60, S. Dist. N.Y.

CHARGE: 502(a)—the label of the article, when shipped, contained false and misleading representations that the article was adequate and effective to regulate and lower the cholesterol of the blood.

DISPOSITION: 5–24–60. Default—destruction.

6227. Leci-Trate tablets and natural iodine tablets. (F.D.C. No. 44405. S. Nos. 93–221/2 P.)

QUANTITY: 116 100-tablet btls., 77 200-tablet btls., 10 500-tablet btls., and 11 1,000-tablet btls. of *Leci-Trate tablets*, and 12 500-tablet btls. and 288 120-tablet btls. of *natural iodine tablets*, at Seattle, Wash.

SHIPPED: 6–8–59 and 12–22–59, from Los Angeles, Calif., by the Vegetrates Co.

LABEL IN PART: "Vegetrates Leci-Trate Tablets (with Rutin & Safflower seed) [or "with Rutin"] Two tablets three times daily supplies: MDR. 150 mg. Lecithin* 12 mg. Rutin* 30 mg. Vitamin C 100% 60 mg. Rose Hips Powder* In a base of Safflower Seed * * * Formulated and Distributed only by Vegetrates Dependable Products, Los Angeles 29, California * * * Each tablet is composed of 100% pure lecithin extracted from soy beans, rutin from buckwheat and Vitamin C (ascorbic acid) in a chocolate-like flavored coating derived from carob," and "Daily Iodine Unit (Natural Iodine Tablets)

Source: Pure Dehydrated Pacific Kelp (Macrocystic-Pyrifera), which supplies iodine in its natural form, together with excipients."

ACCOMPANYING LABELING: Leaflets entitled "Daily Iodine Unit."

LIBELED: 3-29-60, W. Dist. Wash.

CHARGE: *Leci-Trate tablets*, 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective as a lipotropic agent in the blood vessels and to supply important amounts of unsaturated fatty acids, thus to favorably affect the blood circulatory system.

Natural iodine tablets, 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of ill health and serious diseases; chronic state of border-line nutrition; enlargement of the thyroid; goiter; infections; miscarriages; inadequate supply of milk of nursing mothers; fatigue of adolescence; and that the article would stimulate the normal growth of bones, hair, and skin, the normal development of the brain, and sexual development; maintain a normal pregnancy; and promote general health, growth, and development of man; and 502(e)(1)—the label of the article failed to bear the common or usual name of the article, namely, kelp tablets.

DISPOSITION: 5-31-60. Default—destruction.

6228. Ex Ulcer tablets and Jensen's Formulae tablets. (F.D.C. No. 44439. S. No. 43-807 R.)

QUANTITY: 4,300 tablets in bulk drums and 286 50-tablet btls. of *Ex Ulcer tablets*, and 2 50-tablet btls. of *Jensen's Formulae tablets*, at Butte, Mont., in possession of Elmeton Pharmacal Co.

SHIPPED: 2-8-60, from Portland, Oreg., by Haack Laboratories, Inc.

LABEL IN PART: (Drum) "Haack Laboratories, Inc., Portland, Oregon * * * Manufactured for: Jensen Drug Company, Butte, Montana * * * 25,800 tablets * * * P.F. A-5213 Bismuth Subnitrate 7½ grains Bismuth Subgallate 5 grains Magnesium Oxide 5 grains Oil of Peppermint qs 51001"; and (btls.) "Ex Ulcer Tablets * * * Elmeton Pharmacal Co. Butte, Montana San Francisco, Calif. Contains: Bismuth Oxygallate, Bismuth Oxynitrate, Magnesium Hydroxide, Mint Oil Directions" and "Jensen's Formulae Tablets Elmeton Pharmacal Co. Butte, Montana * * * Contains Bismuth Oxygallate, Bismuth Oxynitrate, Magnesium Hydroxide, Mint Oil. Directions."

RESULTS OF INVESTIGATION: The tablets in the bottles were repacked by the dealer from bulk stock which had been shipped as described above.

LIBELED: 4-22-60, Dist. Mont.

CHARGE: 502(a)—the labels of the tablets, while held for sale, contained false and misleading representations that the tablets were an adequate and effective treatment for ulcers and other serious conditions of the stomach.

DISPOSITION: 5-18-60. Default—destruction.

6229. Queen Bee capsules. (F.D.C. No. 44407. S. No. 77-192 P.)

QUANTITY: 327 45-capsule btls. and 58 90-capsule btls. at Seattle, Wash.

SHIPPED: 2-5-60, from Los Angeles, Calif., by Retail Drug Service, Inc.

LABEL IN PART: (Btl.) "Queen Bee Brand Vitamins Minerals and Royal Jelly * * * A dietary supplement (see side panel) * * * One (1) Queen Bee Brand capsule three (3) times a day, or as directed by the physician. Each day's supply contains 6000 mcg. of certified pure, whole, natural Royal Jelly * * * Caltex Distributors, Inc., Dallas, Texas."

ACCOMPANYING LABELING: Leaflets entitled "Royal Jelly The 'Miracle Food' of the Queen Bee."

LIBELED: 3–29–60, W. Dist. Wash.

CHARGE: 502(a)—the label accompanying the article, when shipped, contained false and misleading representations that the article was effective in killing disease-causing germs, was an antibiotic like penicillin; would stop the growth of pus-producing infectious germs that cause boils, carbuncles, and abscesses; was effective against fungus that cause ringworm of the scalp, athlete's foot, and other maladies; would stop the growth of cancer cells; arrest leukemia; and had anti-tumor activity.

DISPOSITION: 5–31–60. Default—destruction.

6230. Yeast culture wafers. (F.D.C. No. 44605. S. No. 43–668 R.)

QUANTITY: 230 cases, each containing 72 60-wafer btls. at Seattle, Wash., in possession of Genius, Inc.

SHIPPED: Between 3–1–60 and 4–5–60, from Chillicothe, Ill., by Newhaven Laboratories.

LABEL IN PART: (Btl.) "Western Yeast Culture A Food Supplement with Vitamin B Complex and Vitamins A and D * * * Each Wafer contains * * * with Vitamin B Complex and Vitamin A and D additions to Vitamins as listed below Vitamin B_1 (Thiamin Mononitrate) 2 mg. Vitamin B–2 (Riboflavin) 2.4 mg. Vitamin B–6 (Pyridoxine Hydrochloride) 1 mg. Vitamin B–12 Cobalamin Concentrate NF) 1 microg. Calcium Pantothenate 2 mg. Acid Nicotinic 10 mg. Folic Acid 0.25 mg. Vitamin A (Acetate) 4000 Units Vitamin D (Irridated Yeast) 600 Units Powdered Sugar Excipient added * * * The need for Folic Acid, Pyridoxine Hydrochloride, Calcium Pantothenate and Vitamin B–12 has been established * * * Distributed by Western Products South 5th and Broadway, Tacoma 2, Washington."

ACCOMPANYING LABELING: Leaflets entitled: "The Western Yeast Story," "S–1 Direct Retail Buyer," "S–2 Wholesale Buyer" and "S–3 Retailer"; placards entitled "As advertised by Bob Hale"; and cards reading in part "I'll Send You $2.50 for this card."

RESULTS OF INVESTIGATION: The circulars and placards were designed and printed by Genius, Inc., and were used in promoting sales of the article.

LIBELED: 6–10–60, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations which suggested and implied that the article had a beneficial effect on the involuntary muscles of the digestive tract, and the nerve and circulatory systems; that it provided greatly increased energy; that it aided digestion, and elimination; increased resistance to disease; prevented skin disorders; that it contained anti-infection properties; aided in normal growth, and provided health to the mucous membranes of the body; was very essential for the maintenance of health and well-being; helped maintain high resistance to the common cold, sickness, and infections; overcame a tired rundown feeling, and lack of energy; gave added energy and drive; and cleared up bad complexion; and the labeling statements "Little Golden Nuggets of Pure Health" and "Naturally Grown" also were false and misleading.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 6-17-60. Consent—claimed by Genius, Inc., of Seattle, Wash., and relabeled.

6231. Alfalfa seed. (F.D.C. No. 44564. S. No. 4-024 R.)

QUANTITY: 13 100-lb. bags and 110 1-lb. ctns. at Richmond, Va., in possession of T. W. Wood & Sons.

SHIPPED: 9-4-59 and 2-1-60, from Yuma, Ariz.

LABEL IN PART: (Bag) "Alfalfa for Tea" or "Common * * * Alfalfa"; (ctn.) "One Pound Net Wood's Hollybrook Brand * * * Alfalfa Seed," (top) "T. W. Wood & Sons * * * Richmond, Va." and (bottom) "Grown in California."

ACCOMPANYING LABELING: Catalog entitled "Spring Catalog 1960."

RESULTS OF INVESTIGATION: The article in the 1-lb. cartons was repacked and labeled by the dealer from the bulk bags shipped as described above.

LIBELED: 5-11-60, E. Dist. Va.

CHARGE: 502(a)—while held for sale, the label statement "Grown in California" was false and misleading as applied to a product which was grown in Arizona; and the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for arthritis and rheumatism.

DISPOSITION: 6-8-60. Consent—claimed by T. W. Wood & Sons, Richmond, Va., and relabeled.

6232. Protein wafers. (F.D.C. No. 44557. S. No. 29-202 R.)

QUANTITY: 98 btls., each containing 300 wafers, at Council Bluffs, Iowa, in possession of Dwarfies, Inc.

SHIPPED: 9-25-57, from Los Angeles, Calif.

LABEL IN PART: (Btl.) "'Miss Physical Fitness' Dixie Q Balanced Hi Protein Wafers * * * Eat Like Candy! Lemon and Malt Flavors * * * Internationally Chosen 'Miss Physical Fitness' * * * Each 12 Wafers Contain: % Adult MDR Thiamine (vitamin B-1) 2.0 mgm. 200% Riboflavin (vitamin B-2) 2.5 mgm. 208% Pyridoxine HCl (B-6) 1.0 mgm. * * * Vitamin B-12 (cobolamin conc.) 3.0 mcgm. * * * Niacinamide 10.0 mgm. 100% Calcium Pantothenate 2.0 mgm. * * * Vitamin E (dl-A-Tocopheryl acid succinate) 6.0 Int. Units * * * Need in human nutrition not established. * * * Packed by Vitamin Div. Dwarfies Corp. Council Bluffs, Iowa."

RESULTS OF INVESTIGATION: The article was shipped in bulk drums as described above and after its receipt at Council Bluffs, Iowa was repacked by Dwarfies, Inc., into the bottles described above.

LIBELED: 5-5-60, S. Dist. Iowa.

CHARGE: 502(a)—while held for sale, the label statements "Miss Physical Fitness" and "Internationally Chosen 'Miss Physical Fitness'" and the vignette depicting a physically fit woman represented and suggested that the article would promote physical fitness and a properly proportioned figure, which statements and representations were false and misleading since they were contrary to fact.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 6-7-60. Default—destruction.

6233. LD-Lax. (F.D.C. No. 44443. S. No. 12-606 R.)

QUANTITY: 13 cases, each containing 10 10-oz. cans, at Chicago, Ill.

SHIPPED: 2-26-60, from Battle Creek, Mich., by Battle Creek Food Co.

LABEL IN PART: (Can) "Battle Creek LD-Lax Ingredients: Psyllium Gum, Lactose, Dextrins, Soy Flour, Flavorings and Tricalcium Phosphate. Sodium 0.15 mgs. per 100 gms.; negligible in quantities recommended * * * Packed by the Battle Creek Food Company Battle Creek, Michigan."

RESULTS OF INVESTIGATION: Examination showed that the article contained 28 mgs. of sodium in each 100 grams.

LIBELED: 4-21-60, N. Dist. Ill.

CHARGE: 502(a)—when shipped, the label statement "Sodium 0.15 mgs. per 100 gms." was false and misleading; in addition the label contained false and misleading representations that the article was adequate and effective for reducing, to decrease the capacity and desire for food, and as an intestinal sweetener; and that the article was a food supplement.

DISPOSITION: 6-30-60. Default—destruction.

6234. Slimdex tablets. (F.D.C. No. 44433. S. No. 4-019 R.)

QUANTITY: 79 50-tablet btls. and 182,000 tablets at Baltimore, Md., in possession of Carroll Chemical Co., Inc.

SHIPPED: On 9-15-59 and 2-24-60, powdered phenylpropanolamine hydrochloride was shipped in bulk containers from New York, N.Y., and thereafter used by Carroll Chemical Co., Inc., in the manufacture of the above-mentioned tablets.

LABEL IN PART: (Btl.) "Slimdex Carroll * * * Each tablet contains: Phenylpropanalamine Hydrochloride 25 mg. The Carroll Chemical Co. Baltimore Md."

ACCOMPANYING LABELING: Counter display carton reading in part "Carroll Slimdex * * * Control Your Appetite Lose Weight-Scientifically-Safely."

LIBELED: 4-18-60, Dist. Md.

CHARGE: 502(a)—while held for sale, the name of the article and certain statements in the labeling of the article contained false and misleading representations that the article was capable of making the user become slender; that the article was capable of controlling the appetite effectively and thereby aiding in weight reduction; and that the article was capable of causing the user to lose weight by controlling the appetite.

DISPOSITION: 5-13-60. Default—destruction.

6235. X-Drin tablets. (F.D.C. No. 43786. S. No. 66-403 P.)

QUANTITY: 54 ctns., each containing 12 btls., at Lackawanna, N.Y.

SHIPPED: 8-18-59, from Hollywood, Fla., by Pharmex, Inc.

LABEL IN PART: (Ctn.) "Appetite Depressant * * * To Lose Weight * * * Curb Your Appetite"; (btl.) "21 Tablets X-Drin A True Appetite Depressant Banner Distributors * * * Erie, Penna Each Tablet Contains: Phenylpropanolamine Hydrochloride 25 MG * * * 38158."

LIBELED: 10-29-59, W. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations and suggestions that the article was effective as an appetite depressant in the management of obesity.

DISPOSITION: 11-25-59. Default—destruction.

6236. Honey. (F.D.C. No. 44544. S. No. 29–817 R.)

QUANTITY: 250 cases, each containing 6 3-lb. jars, at Minneapolis, Minn., in possession of Honey Sales Co.

SHIPPED: 4–6–60, from David City, Nebr.

LABEL IN PART: (Jar) "Land O'Clover Genuine Natural Honey Nothing added . . . Nothing taken away * * * Learn how Honey and other Natural foods give you more energy than zip pills, sounder sleep than sedatives, and lower tension than tranquilizers, etc. Obtain the amazing new book "Folk Medicine" by D. C. Jarvis, M.D. * * * Honey Sales Company, 2817 N. 2nd St., Minneapolis 11, Minnesota."

ACCOMPANYING LABELING: Books entitled "Folk Medicine" by D. C. Jarvis, M.D.

RESULTS OF INVESTIGATION: The article in the jars was repacked and labeled by the dealer after removal from 5-gal. cans shipped as described above.

LIBELED: 4–26–60, Dist. Minn.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was adequate and effective for the treatment of arthritis; digestive disorders; belching; constipation; high blood pressure; chronic fatigue; headaches, including migraine headache; infectious diseases, including typhoid; broncho-pneumonia; peritonitis; pleurisy; dysentery; fungus diseases; heart disease; diabetes; insomnia; sterility; nervousness; tension; irritability; itching scalp and skin; numbness; cold hands and feet; dizziness; mental retardation; tooth decay; falling hair; breaking fingernails; hay fever; callouses and corns; slow healing of cuts and bruises; pimples; tic; cramps in muscles; blocked and swollen lymph glands; coughs; colds; sinus infection; infant colic; bed-wetting; hangovers; alcoholism; and that the article would provide vigor, promote longevity, control and reduce weight without restrictions of diet; and reduce or eliminate the difficulties of old age.

DISPOSITION: 6–1–60. Consent—claimed by Honey Sales Co., Minneapolis, Minn., and relabeled.

6237. Honegar. (F.D.C. No. 44568. S. No. 3–427 R.)

QUANTITY: 50 1-pt. btls. at Washington, D.C.

SHIPPED: 3–28–60, from New York, N.Y., by B. T. Babbitt, Inc.

LABEL IN PART: (Btl.) "Undiluted Pure Honey Unpasteurized & Unfiltered Apple Cider Vinegar * * * HONEGAR * * * Honegar Division, 625 Madison Ave., New York 22, N.Y."

ACCOMPANYING LABELING: Books entitled "Folk Medicine" by D. C. Jarvis, M.D., and a poster reading in part "Discover . . . The Secrets of Good Health and Long Life . . . Astonishing Facts About * * * Folk Medicine A Vermont Doctor's Guide to Good Health."

LIBELED: 5–9–60, Dist. Columbia.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article, namely, the window display poster and the book entitled "Folk Medicine" accompanying the article, contained false and misleading representations that the article was adequate and effective for the treatment and prevention of arthritis; digestive disorders; belching; vomiting and diarrhea from food poisoning; constipation; obesity; high blood pressure; chronic fatigue and headaches, including migraine headaches; all infectious diseases, including typhoid; broncho-pneumonia; peritonitis; pleurisy; dysentery; fun-

gus diseases; common cold; chickenpox; and measles; all childhood diseases; heart disease; heart attacks; essential hypertension; diabetes; insomnia; sterility; difficult labor; morning sickness; nervousness; tension; irritability; itching scalp and skin; numbness; cold hands and feet; dizziness; mental retardation; tooth decay; falling hair; breaking fingernails; paranasal sinusitis; seepage from sinuses; asthma; hay fever; facial neuralgia; retarded growth; pyelitis; thickened blood; ringing in ears; impaired hearing; Meniere's syndrome; callouses and corns; slow healing of cuts and bruises; pimples; tic; cramps in muscles; blocked and swollen lymph glands; cough; infant colic; bed wetting; hangovers; alcoholism; and to provide vigor; promote longevity; maintain good health from the cradle to the grave; to control and reduce weight without restrictions of diet; and to reduce or eliminate the difficulties of old age; and 502(b)(1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 6–27–60. Default—one bottle and the book "Folk Medicine" were delivered to the Food and Drug Administration and the remainder of the article and its accompanying labeling was destroyed.

6238. Pleasant Aire devices. (F.D.C. No. 44565. S. No. 3–397 R.)

QUANTITY: 86 devices consisting of 67 Model S (room size) devices, 18 Model L dual devices, and 1 Model F furnace device, at Washington, D.C.

SHIPPED: 1–28–60, from Bethesda, Md., by Pleasant Aire, Div. of Viritrol Corp.

LABEL IN PART: (Devices) (front) "Pleasant Aire," (back) "Caution Protect Your Eyes!"

ACCOMPANYING LABELING: Leaflets headed "Just Plug in Pleasant Aire" and a poster headed "Lansburgh's First in the Nation to introduce."

RESULTS OF INVESTIGATION: The Model S device was a portable-type cabinet containing a fan, three ultra-violet lamps, and a filter. The dual unit (Model L) contained two blower fans, 5 ultra-violet lamps, and two filters. The furnace unit (Model F) consisted of a transformer and ballast in a metal case and an ultra-violet bactericidal tube to be placed inside the cold air return duct of a furnace.

LIBELED: 5–9–60, Dist. Columbia.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for relieving hay fever, sinus, asthma, and airborne allergies; protecting against many germ and virus produced diseases; preventing spread of contagious airborne germs and viruses; reducing danger of airborne infection; and sanitizing the air.

DISPOSITION: 5–19–60. Consent—claimed by Viritrol Corp., and relabeled.

6239. Niblack System spot reducing devices. (F.D.C. No. 44556. S. No. 27–708 R.)

QUANTITY: 10 devices of 3 different styles consisting of 4 Salon Table Units bearing the letters "NS," 5 Salon Pony Units bearing the letters "NS" and 1 Home Pony Unit labeled "The Niblack System Home Pony * * * NS," at Minneapolis, Minn.

SHIPPED: From Denver, Colo., by Niblack System, Inc. The Salon Table Units and Salon Pony Units were shipped some time in 1952, and the Home Pony Unit was shipped on 3–9–60.

ACCOMPANYING LABELING: Pamphlets entitled "How To Keep Your Figure With The Niblack Home Pony" and "Niblack System The World's Greatest Method of Scientific Spot Reducing," and leaflets entitled "Niblack Slenderizing System."

RESULTS OF INVESTIGATION: The device was an appliance containing a series of rollers which were caused to rotate by a motor-driven belt. The patient was massaged by placing the portions of the anatomy, through various positions, against the rotating rollers.

LIBELED: 5–2–60, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling accompanying the devices contained false and misleading representations that the devices were an adequate and effective treatment for reforming the body; removing surplus inches in specific areas; keeping the body firm and vibrant; spot reducing; relieving menstrual period tension; reducing weight; proportioning the figure; restoring muscle tone; and aiding faulty elimination.

DISPOSITION: 5–12–60. Consent—claimed by H. C. Fischer, t/a Niblack Slenderizing System, Minneapolis, Minn. The article was relabeled.

6240. Contour Chair-lounge. (F.D.C. No. 42885. S. No. 49–402 P.)

QUANTITY: 31 chairs at Seattle, Wash., in possession of Finch's Original Contour Chairs.

SHIPPED: Between 10–4–58 and 2–7–59, from St. Louis, Mo., by Contour Chair-Lounge Co., Inc.

LABEL IN PART: "Contour Chair-Lounge Co., Inc., * * * with viverator, St. Louis, Mo. Model * * * Serial * * * Pre-moulded to fit you * * * Heat & viv."

ACCOMPANYING LABELING: Leaflets entitled "Contour Revolutionizes Relaxation," "Holiday," "Finch's Relaxing Miracle," and "Pre-Moulded to Fit You"; placard entitled "Only Contour Relaxes You in 7 Vital Ways"; and folders containing testimonials.

RESULTS OF INVESTIGATION: The article was an upholstered lounge or reclining-type chair, adjustable to several positions, and containing an electric motor capable of providing controlled degrees of vibration. Some chairs were also equipped with a controlled heating unit.

The leaflets entitled "Finch's Relaxing Miracle" were prepared by the dealer.

LIBELED: 3–16–59, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for releasing one of nervous tension and fatigue to take the load off of the heart; providing the "no drug" way to "tranquilize"; relieving heart trouble, insomnia, asthma, sciatica, pneumonia, arthritis, rheumatism, edema, varicose veins, and other disorders; stimulating the processes of the functional organs and glands; restoring radiant beauty and energy; achieving correct posture; providing general good health; relieving high blood pressure, chronic constipation, erysipelas, baldness, kidney conditions, indigestion, skull fracture, respiratory diseases, dropsy, paralysis of limbs, Buerger's disease, coronary thrombosis, Parkinson's disease, neuritis; and preventing children's diseases.

DISPOSITION: 12–18–59. Consent—claimed by Loran W. Finch, Seattle, Wash., and relabeled.

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PRODUCTS

[1] (6202, 6208) Seizure contested.
[2] (6213) Seizure contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[2] (6213) Seizure contested. Contains opinion of the court.

[1] (6202, 6208) Seizure contested.

U.S. GOVERNMENT PRINTING OFFICE: 1961

D.D.N.J., F.D.C. 6241–6280

Issued March 1961

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6241–6280

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1) and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C.

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582709—61

VIOLATIVE SALES OF PRESCRIPTION DRUGS

6241. (F.D.C. No. 43717. S. Nos. 75–805 P, 75–810 P.)

INFORMATION FILED: 2–3–60, W. Dist. Mo., against **Ralph M. Duncan, t/a Duncan Truck Stop, Jasper, Mo.**

CHARGE: Between 9–1–59 and 10–27–59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 5–2–60. $1,000 fine, plus costs, and probation for 1 year.

6242. (F.D.C. No. 44338. S. Nos. 29–316 P, 46–726 P, 46–793 P, 46–795 P, 46–800 P, 73–589 P, 73–604 P, 73–616 P.)

INFORMATION FILED: 8–9–60, N. Dist. Miss., against **Thomas Brit Chism, t/a Brit Chism's Truck Stop, Shannon, Miss., and Mrs. Dorothy Chism.**

CHARGE: Between 6–10–59 and 9–7–59, *amphetamine sulfate tablets* were dispensed 5 times and *dextro-amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by both defendants.

DISPOSITION: 9–9–60. Each defendant fined $50.

6243. (F.D.C. No. 44625. S. Nos. 5–861/7 P.)

INFORMATION FILED: 8–22–60, W. Dist. Va., against **Mrs. Lillian M. Taylor, t/a 58 Truck Stop, Danville, Va., and Robert Hughey and Miles E. Kiester, Jr. (employees).**

CHARGE: Between 4–6–59 and 9–18–59, *amphetamine sulfate tablets* were dispensed 4 times and *dextro-amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by Mrs. Taylor to all counts; by Kiester to 3 counts involving *amphetamine sulfate tablets* and 1 count involving *dextro-amphetamine sulfate tablets;* and by Hughey to 2 counts involving *dextro-amphetamine sulfate tablets.*

DISPOSITION: 9–12–60. Taylor—$500 fine; Kiester and Hughey—probation for 3 years each.

6244. (F.D.C. No. 42426. S. Nos. 45–692 M, 67–125 M, 67–128/30 M, 4–081/9 P.)

INFORMATION FILED: 3–5–59, E. Dist. N.C., against **William Monroe Abbott, Earl Holloman, Gilbert Thompson, and Bill Hinton (employees of a truck stop near Selma, N.C.).**

CHARGE: Between 5–2–57 and 4–17–58, *amphetamine sulfate tablets* were dispensed once (count 1), and *amphetamine hydrochloride tablets* were dispensed 13 times (counts 2 through 14) without a prescription.

PLEA: Not guilty by Holloman to counts 2, 3, and 4. Guilty by Abbott to count 1 and counts 9 through 14; by Thompson to counts 5, 7, 8, and 12; and by Hinton to count 6.

DISPOSITION: On 8–15–60, the case against Defendant Earl Holloman came on for trial before the court without a jury. On 8–16–60, the defendant was found guilty by the court and was fined $150.

On 8–16–60, Abbott was fined $300; Thompson $250; and Hinton $100. In addition, each of the four defendants was placed on probation for 2 years.

6245. (F.D.C. No. 43253. S. No. 1-243 P.)

INDICTMENT RETURNED: 11-3-59, N. Dist. Ga., against **Charles Frank Gray, t/a Charles' Truck Stop, Cumming, Ga.**

CHARGE: On 3-6-59, *amphetamine sulfate tablets* were dispensed once without a prescription.

DISPOSITION: The defendant having entered a plea of not guilty, the case came on for trial on June 29, 1960. After the Government had introduced most of its evidence the defendant changed his plea to guilty. On 7-14-60, the court placed the defendant on probation for 2 years.

6246. (F.D.C. No. 42443. S. Nos. 4-100/3 P.)

INFORMATION FILED: 3-5-59, E. Dist. N.C., against **Huston Ray, Ed Smith, and William E. Tart, Dunn, N.C.**

CHARGE: Between 7-8-58 and 7-23-58, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty by Ray to counts 1 and 2; by Smith to counts 1, 2, and 3; and by Tart to count 4.

DISPOSITION: 8-19-60. Ray—$25 fine; Smith—$150 fine; and Tart—$500 fine. Each of the three defendants was placed on probation for 2 years.

6247. (F.D.C. No. 43212. S. Nos. 9-591 P, 9-594 P, 10-485 P, 10-499 P, 10-787 P, 10-790 P.)

INFORMATION FILED: 7-23-59, W. Dist. Pa., against **Jack F. Gambino, t/a Jack's Truck Stop, Erie, Pa.**

CHARGE: Between 10-30-58 and 2-19-59, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6-28-60. The defendant was fined $1, plus costs, and sentenced to 1 year and 1 day in jail on each count, the sentences to run concurrently. The jail sentence was suspended and the defendant was placed on probation for 3 years.

6248. (F.D.C. No. 44329. S. Nos. 59-466/8 P.)

INFORMATION FILED: 6-2-60, E. Dist. Va., against **Raymond White and Willie Epps, Amelia, Va.**

CHARGE: Between 8-27-59 and 9-3-59, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by White to 2 counts of the information and by Epps to 1 count.

DISPOSITION: 6-14-60. White—$20 fine; Epps—$20 fine.

6249. (F.D.C. No. 43255. S. Nos. 1-233 P, 2-156 P.)

INDICTMENT RETURNED: 11-3-59, N. Dist. Ga., against **Clarence Andrew Tomlin, t/a Tomlin's Drive-In, Gainesville, Ga.**

CHARGE: On 11-12-58, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Not guilty.

DISPOSITION: On 6-13-60, the case came on to trial before the court and jury and on 6-14-60, the jury returned a verdict of guilty. On 6-23-60, the defendant was placed on two years probation.

6250. (F.D.C. No. 43259. S. Nos. 1–560 P, 44–112 P.)

INDICTMENT RETURNED: 11–3–59, N. Dist. Ga., against **Garland Bradford Barnes, t/a T & C Cafe, Gainesville, Ga., and Price Pinion (employee).**

CHARGE: On 10–28–58, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty by both defendants.

DISPOSITION: 6–23–60. Barnes—probation for 2 years; Pinion—1 year in prison suspended, and probation for 2 years.

6251. (F.D.C. No. 44289. S. Nos. 15–754 P, 15–982 P.)

INFORMATION FILED: 4–8–60, S. Dist. Ind., against **Paul B. Brokamp, t/a Trucker's Haven, Stilesville, Ind., and James Lawson (employee).**

CHARGE: Between 9–24–59 and 9–29–59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Not guilty by Brokamp; guilty by Lawson.

DISPOSITION: The case against Brokamp came on for trial on 6–22–60. After the Government had presented its testimony, Brokamp changed his plea to guilty. On 6–27–60, the court imposed sentence against Lawson of 1 year in jail which was suspended, and placed him on probation for 1 year. On 8–5–60, the court fined Brokamp $1,000, plus costs, gave him a suspended sentence of 6 months in jail, and placed him on probation for 1 year.

6252. (F.D.C. No. 44292. S. Nos. 71–242/4 P.)

INFORMATION FILED: 3–4–60, S. Dist. Ind., against **Valley Drive In (a partnership), Knightstown, Ind., James I. Voris and Richard Voris.**

CHARGE: Between 10–27–59 and 10–29–59, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on for trial before the court and jury on 6–27–60. The trial was concluded on 6–29–60, with the return of the jury's verdict of guilty against each defendant, and on the same day the court sentenced the defendants as follows: partnership—$500 fine, plus costs; James Voris—$1,000 fine, plus costs, imprisonment for 1 year suspended, plus a 10-day jail sentence to be served, and probation for 1 year; Richard Voris—imprisonment for 1 year suspended, and probation for 1 year.

6253. (F.D.C. No. 43221. S. Nos. 9–578/9 P, 9–581/2 P, 9–595 P, 9–729 P, 9–912 P, 9–914 P, 10–007 P, 10–486 P.)

INFORMATION FILED: 8–13–59, W. Dist. N.Y., against **Lucille A. Stein, t/a 5th Wheel Truck Stop, Ripley, N.Y., and Hazel Swoger (waitress).**

CHARGE: Between 9–17–58 and 12–4–58, *amphetamine sulfate tablets* were dispensed 9 times and *dextro-amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Not guilty by Stein to all counts; guilty by Swoger to one count involving the *amphetamine sulfate tablets.*

DISPOSITION: On 5–25–60, the case against Defendant Stein came on for trial before the court and a jury and on 5–27–60, the jury rendered a verdict of guilty.

On 6–20–60, Defendant Stein was given a suspended sentence of 1 year in jail on all counts. In addition, Defendant Stein was placed on 2 years pro-

bation. Swoger was given a 3 months jail sentence which was suspended and placed on probation for 3 months.

6254. (F.D.C. No. 43254. S. Nos. 1-235 P, 2-122 P, 2-158 P, 44-113 P.)

INDICTMENT RETURNED: 11-3-59, N. Dist. Ga., against **Marvin M. Graham, t/a Friendly Tavern, Forest Park, Ga.**

CHARGE: Between 10-30-58 and 11-14-58, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Not guilty.

DISPOSITION: The case came on to trial on 1-27-60, before the court and a jury. On 1-28-60, the jury returned a verdict of guilty. Thereafter, on 2-10-60, the defendant was sentenced to 1 year's imprisonment and fined $250. The prison sentence was suspended upon payment of the fine and the defendant was placed on probation for 2 years.

6255. (F.D.C. No. 44639. S. No. 59-539 P.)

INFORMATION FILED: 8-4-60, S. Dist. W. Va., against **Sidney McMillen, Jr., Princeton, W. Va.**

CHARGE: On 10-9-59, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9-26-60. Imprisonment for 1 year.

6256. (F.D.C. No. 44355. S. Nos. 3-255 P, 72-073 P.)

INFORMATION FILED: 8-15-60, W. Dist. S.C., against **James Harold Carpenter (a truck stop employee), Rock Hill (York County), S.C.**

CHARGE: On 11-4-59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9-19-60. $100 fine, 1 year in prison suspended, and probation for 5 years.

6257. (F.D.C. No. 44347. S. Nos. 3-254 P, 87-308 P.)

INFORMATION FILED: 8-15-60, W. Dist. S.C., against **Berle Anderson Craft, t/a By Pass Truck Stop, Rock Hill, S.C.**

CHARGE: Between 11-4-59 and 11-22-59, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9-9-60. $100 fine, 1 year in prison suspended, and probation for 5 years.

6258. (F.D.C. No. 44339. S. Nos. 29-315 P, 46-724/5 P, 46-796 P, 46-799 P, 73-605 P, 73-610 P.)

INFORMATION FILED: 6-16-60, N. Dist. Miss., against **Samuel C. Woolbright, Jr., t/a Bill Kiefer Truck Service, Verona, Miss., and Henry Osborne.**

CHARGE: Between 6-10-59 and 9-2-59, *amphetamine sulfate tablets* were dispensed 6 times and *desoxyephedrine hydrochloride tablets* were dispensed once without a prescription.

PLEA: Guilty by Woolbright to all counts; by Osborne to 6 counts.

DISPOSITION: 9-23-60. Woolbright—$700 fine and probation for 2 years; Osborne—probation for 3 years.

6259. (F.D.C. No. 43718. S. Nos. 75–801 P, 75–811/2 P.)

INFORMATION FILED: 3–2–60, E. Dist. Ark., against **Ben L. Bradford (partner in the partnership of Auten's Truck Stop), North Little Rock, Ark.**

CHARGE: Between 8–31–59 and 10–27–59, *dextro-amphetamine sulfate tablets* were dispensed twice and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 5–20–60. $150 fine, and 45 days in jail.

6260. (F.D.C. No. 44301. S. No. 80–441/4 P.)

INFORMATION FILED: 5–5–60, N. Dist. Ind., against **Francis R. Weber, t/a Brimfield Truck Stop, Brimfield, Ind., and L. C. Webb (employee).**

CHARGE: Between 10–14–59 and 10–20–59, *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6–28–60. A joint fine of $400, plus costs, was assessed against the defendants. The fine and costs were suspended and the defendants were each placed on probation for 1 year.

6261. (F.D.C. No. 44307. S. Nos. 5–850 P, 59–698/700 P.)

INFORMATION FILED: 5–17–60, W. Dist. Va., against **Robert Gordon Carlan, Galax, Va.**

CHARGE: Between 10–10–59 and 10–26–59, *dextro-amphetamine sulfate tablets* were dispensed twice and *butabarbital sodium tablets* and *pentobarbital sodium capsules* were each dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–26–60. $1,000 fine and probation for 2 years.

6262. (F.D.C. No. 44276. S. Nos. 14–730/3 P.)

INDICTMENT RETURNED: 4–20–60, W. Dist. Mich., against **Cyril Hansen, Grand Rapids, Mich.**

CHARGE: Between 1–23–59 and 1–25–59, *dextro-amphetamine sulfate tablets* and *secobarbital sodium capsules* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–23–60. $300 fine and probation for 4 years.

6263. (F.D.C. No. 42499. S. No. 59–528 P.)

INFORMATION FILED: 8–4–60, S. Dist. W. Va., against **Sidney McMillen, Jr., Princeton, W. Va.**

CHARGE: On 10–16–59, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 9–26–60. Imprisonment for 1 year.

6264. (F.D.C. No. 35620. S. Nos. 82–503 L, 82–506/7 L, 82–598 L, 88–391/2 L.)

INFORMATION FILED: 12–11–57, W. Dist. N.Y., against **Melvin G. Wheeler and Frank W. Ziebro, Rochester, N.Y.**

CHARGE: Between 5–21–54 and 6–1–54, *dextro-amphetamine sulfate capsules* (counts 1, 2, and 3) were dispensed 3 times, *methyltestosterone tablets* (counts

4 and 5) were dispensed twice, and *methantheline bromide tablets* (count 6) were dispensed once upon requests for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere by Wheeler to counts 1, 2, and 4; and by Ziebro to counts 3, 5, and 6.

DISPOSITION: 9–27–60. Wheeler—$600 fine of which $400 was remitted; Ziebro—$600 fine of which $400 was remitted.

6265. (F.D.C. No. 44326. S. Nos. 62–682/6 P.)

INFORMATION FILED: 5–27–60, W. Dist. Mich., against **George G. Love, t/a Love's Cut Rate Drug Store, Grand Rapids, Mich., and Beatrice J. Ingram (employee).**

CHARGE: Between 2–11–59 and 2–20–59, *dextro-amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty by Love to all counts; and by Ingram to 2 counts.

DISPOSITION: 9–2–60. Ingram—$50 fine; Love—$250 fine.

6266. (F.D.C. No. 42460. S. Nos. 4–087/8 P.)

INFORMATION FILED: 3–5–59, E. Dist. N.C., against **Selma Drug Co., Inc., Selma, N.C., and William H. Creech III (vice-president).**

CHARGE: Between 3–27–58 and 4–8–58, *amphetamine hydrochloride tablets* were dispensed twice without a prescription.

PLEA: Guilty by both defendants.

DISPOSITION: 8–16–60. Corporation—$1,250 fine; Creech—$750 fine and probation for 2 years.

6267. (F.D.C. No. 44294. S. Nos. 22–441/9 P.)

INFORMATION FILED: 3–31–60, W. Dist. Mo., against **Stephen H. Langmaid, Kansas City, Mo.**

CHARGE: Between 8–26–59 and 10–15–59, *pentobarbital sodium capsules* and *tablets containing a mixture of amobarbital and amphetamine hydrochloride* were each dispensed once, and *amphetamine sulfate tablets* were dispensed 7 times without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 5–27–60. 3 years probation.

6268. (F.D.C. No. 42477. S. Nos. 28–581/2 P, 28–586 P, 28–591 P.)

INFORMATION FILED: 9–23–59, E. Dist. La., against **Klein's One-Stop Drug Store (a partnership), Gretna, La., and Louis A. Klein (partner).**

CHARGE: Between 8–19–58 and 10–27–58, *phenobarbital tablets* were dispensed 3 times and *Dexedrine Sulfate tablets* were dispensed once upon requests for prescription refills without authorization from a prescriber.

PLEA: Guilty.

DISPOSITION: 7–6–60. A fine of $800 was assessed jointly against the defendants, and in addition, the individual defendant was placed on probation for one year.

6269. (F.D.C. No. 44350. S. Nos. 44–750 P, 44–755 P, 44–762 P, 44–765 P, 72–198 P, 72–200 P, 72–204/6 P.)

INFORMATION FILED: About 8–18–60, M. Dist. Ga., against **Julius Clement Smith, t/a North Highland Pharmacy, Columbus, Ga.**

CHARGE: Between 8–4–59 and 9–21–59, *secobarbital sodium capsules* were dispensed 4 times and *Equanil tablets* were dispensed 5 times upon requests for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere.

DISPOSITION: 9–7–60. $500 fine.

6270. (F.D.C. No. 44349. S. Nos. 44–752 P, 44–757 P, 56–561/3 P, 56–579 P, 71–712/3 P, 72–195 P, 72–197 P.)

INFORMATION FILED: About 8–18–60, M. Dist. Ga., against **H. L. Green, Co., Inc., Columbus, Ga., David Lloyd Thomas (pharmacist), and James Riley Lindsey (employee).**

CHARGE: Between 6–11–59 and 8–14–59, *Equanil tablets* were dispensed 10 times upon requests for prescription refills without authorization from the prescriber.

PLEA: Nolo contendere by the corporation to all counts; by Thomas to 9 counts; and by Lindsey to 6 counts.

DISPOSITION: 9–7–60. Corporation—$300 fine; Thomas—$100 fine; Lindsey—$100 fine.

6271. (F.D.C. No. 43252. S. Nos. 21–502/11 P, 22–661/2 P.)

INFORMATION FILED: 10–6–59, W. Dist. Okla., against **Orren Quinby Kizziar, t/a Broadway Drug, Altus, Okla., and Mildred Kizziar.**

CHARGE: Between 2–27–59 and 3–26–59, *meprobamate tablets* (counts 1, 3, 5, 7, and 10) and *Chloromycetin capsules* (counts 2, 4, 6, 8, and 11) were each dispensed 5 times without a prescription, and *Dexedrine Sulfate tablets* (counts 9 and 12) were dispensed twice upon requests for prescription refills without authorization from a prescriber.

PLEA: Nolo contendere by Orren Quinby Kizziar to all counts; and by Mildred Kizziar to counts 2 through 12.

DISPOSITION: 7–28–60. Both defendants were placed on probation for 5 years. The court imposed the following conditions on the probation of Orren Quinby Kizziar:

(1) That he surrender his pharmacist's license during the period of the probation; and

(2) That he voluntarily go to the Federal hospital in Fort Worth, Tex., for examination and treatment of drug addiction.

6272. (F.D.C. No. 44309. S. Nos. 20–128 P, 55–568 P, 82–841/7 P.)

INFORMATION FILED: 5–12–60, W. Dist. Mo., against **Carl B. Gershon, t/a Gershons Prescriptions, Kansas City, Mo.**

CHARGE: Between 7–25–59 and 8–25–59, *Meprobamate tablets* were dispensed 4 times, *dextro-amphetamine phosphate tablets* were dispensed 3 times, *chlorpropamide tablets* and *penicillin G potassium tablets* were each dispensed once, without a prescription.

PLEA: Guilty.

DISPOSITION: 6–24–60. $900 fine, plus costs, and probation for two years.

6273. (F.D.C. No. 43207. S. Nos. 10–093 P, 10–099 P, 10–455/6 P, 10–544/6 P, 10–763/7 P.)

INFORMATION FILED: 7-17-59, W. Dist. N.Y., against **Bigham Dambach Co., Inc., Buffalo, N.Y., Richard B. Adams (president, treasurer and pharmacist), Clayton Seward and Adam Ferrari (pharmacists).**

CHARGE: Between 12-9-58 and 3-7-59, *Nembutal capsules* (counts 1, 2, 3, 4, and 6) and *Dexedrine Spansule capsules* (counts 5, 7, 8, 11, and 12) were each dispensed 5 times and *Compazine tablets* (counts 9 and 10) were dispensed twice upon requests for prescription refills without authorization from a prescriber.

PLEA: Nolo contendere by the corporation and Adams to all counts; by Seward to counts 7, 9, 11, and 12; and by Ferrari to counts 4 and 8.

DISPOSITION: 7-6-60. The corporation was fined a total of $1,700, of which $1,300 was remitted; Adams was fined a total of $1,700, of which $1,300 was remitted; Seward was fined a total of $600, of which $400 was remitted; and Ferrari was fined $300, of which $100 was remitted.

6274. (F.D.C. No. 44278. S. Nos. 67-817 P, 67-819 P, 67-940 P, 68-144/5 P, 68-161 P.)

INFORMATION FILED: 3-15-60, E. Dist. Pa., against **Leonard L. Frantz, t/a Frantz Prescription Pharmacy, Philadelphia, Pa., and Benjamin Horen (pharmacist).**

CHARGE: Between 8-31-59 and 9-30-59, *Tuinal capsules* and *Metandren Linguets* were each dispensed 3 times upon request for prescription refills without authorization from the prescribers.

PLEA: Guilty by Frantz to 4 counts; and by Horen to 2 counts of the information.

DISPOSITION: 8-9-60. Frantz—$1,500 fine, and probation for 2 years; Horen—probation for 1 year.

6275. (F.D.C. No. 44323. S. No. 62-361/6 P.)

INFORMATION FILED: 5-27-60, W. Dist. Mich., against **Russell L. Greenwold, t/a Greenwold Drug Store, Grand Rapids, Mich.**

CHARGE: Between 2-10-59 and 2-25-59, *Benzedrine Sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 6-20-60. $600 fine.

6276. (F.D.C. No. 44273. S. Nos. 43-779 P, 43-843 P, 43-845 P, 43-847 P, 43-850 P, 43-852/3 P.)

INFORMATION FILED: 2-26-60, Dist. Colo., against **Staab's Sherman Plaza Drug, Inc., Denver, Colo., and Rudolph L. Staab (president of the corporation).**

CHARGE: Between 2-25-59 and 4-2-59, *Doriden tablets* and *Dexedrine Sulfate tablets* were each dispensed twice, *V-Cillin K tablets* were dispensed once upon requests for prescription refills without authorization from a prescriber, and *V-Cillin capsules* and *thyroid tablets* were each dispensed once without a prescription.

PLEA: Guilty by the corporation to all counts of the information and by the individual to the count involving *thyroid tablets.*

DISPOSITION: 6-10-60. Corporation—$700 fine; individual—$250 fine.

6277. (F.D.C. No. 44331. S. Nos. 50-043/4 P, 71-230 P.)

INFORMATION FILED: 7-6-60, S. Dist. Ind., against **Beverly Walters, Sullivan, Ind.**

CHARGE: Between 9–3–50 and 9–23–59, *desoxyephedrine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 7–21–60. Six months imprisonment on each count suspended, and probation for 1½ years.

6278. (F.D.C. No. 44313. S. Nos. 15–751/2 P, 50–045 P, 71–229 P, 71–232 P, 71–238 P.)

INFORMATION FILED: 6–28–60, N. Dist. Ind., against **Sue Wintrode, Marion, Ind.**

CHARGE: Between 9–2–59 and 9–23–59, *desoxyephedrine hydrochloride tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 9–8–60. Six months imprisonment on each count suspended, and probation for 2 years.

6279. (F.D.C. No. 43218. S. Nos. 33–021/2 P.)

INFORMATION FILED: 3–25–60, S. Dist. N.Y., against **Leonard Drug Co., Inc., New York, N.Y., Leonard Stein (president), and James Adams (pharmacist).**

CHARGE: Between 11–28–58 and 12–10–58, *Proloid tablets* were dispensed twice without a prescription.

PLEA: Guilty by the corporation and Stein to all counts; and by Adams to one count.

DISPOSITION: 9–29–60. Corporation—$1 fine; Stein—$500 fine; Adams—$250 fine.

6280. (F.D.C. No. 43232. S. Nos. 19–601 P, 19–679 P.)

INFORMATION FILED: 9–1–59, Dist. Colo., against **Robert S. Logan, t/a Logan Drug Store No. 2, Pueblo, Colo.**

CHARGE: Between 11–20–58 and 12–2–58, *V-Cillin K tablets* and *meprobamate tablets* were each dispensed once upon requests for prescription refills without authorization from the prescriber.

PLEA: Guilty.

DISPOSITION: 9–23–60. $200 fine.

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PRODUCTS

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SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6244, 6245, 6249, 6251–6254) Prosecution contested.

[1] (6244, 6245, 6249, 6251–6254) Prosecution contested.

[1] (6244, 6245, 6249, 6251–6254) Prosecution contested.

U.S. GOVERNMENT PRINTING OFFICE: 1961

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6281–6300

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *March 7, 1961.*

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VIOLATIVE SALES OF PRESCRIPTION DRUGS

6281. (Inj. No. 371.)

COMPLAINT FOR INJUNCTION FILED: 1–13–60, S. Dist. Miss., against **Joseph W. Stringer, Stringer, Miss.**

CHARGE: The complaint alleged that the defendant was a doctor of medicine who was engaged in the business of selling and dispensing *secobarbital sodium capsules* and *pentobarbital sodium capsules;* that he caused such drugs, while held for sale after shipment in interstate commerce, to be dispensed to persons with whom he had no bona fide relationship of physician and patient; and that the defendant, by causing the dispensing of such drugs to those persons, caused the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs.

DISPOSITION: On 1–22–60, the defendant having consented, the court issued a decree of permanent injunction, enjoining the defendant from directly or indirectly dispensing, and causing to be dispensed, *pentobarbital sodium capsules, secobarbital sodium capsules,* and any other drugs within the meaning of 503(b)(1), while held for sale after shipment in interstate commerce, unless and until:

(a) a bona fide relationship of physician and patient is established between the defendant and the person to whom any one of such drugs is to be dispensed; and

(b) a prescription for the drug, which is to be dispensed to such person, is written and held in file by the defendant.

6282. (F.D.C. No. 44353. S. Nos. 26–783 M, 26–786 M, 26–793/5 M, 29–711 P.)

INFORMATION FILED: 8–22–60, E. Dist. La., against **Ben T. Wood, t/a United Truck Stop, Slidell, La., and Howard P. Wood (employee).**

CHARGE: Between 4–5–57 and 9–15–58, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–9–60. Each defendant was fined $500, sentenced to 1 year in jail, which was suspended, and placed on probation for 2 years.

6283. (F.D.C. No. 43729. S. Nos. 18–545/6 P.)

INFORMATION FILED: 3–1–60, W. Dist. Tex., against **David C. Rice (a truck stop employee), Canutillo, Tex.**

CHARGE: On 11–7–58, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–25–60. Jail sentence of 1 year suspended and defendant placed on probation for 1 year.

6284. (F.D.C. No. 43689. S. Nos. 1–245 P, 1–257 P, 56–332 P, 56–355 P.)

INFORMATION FILED: 12–11–59, S. Dist. Ga., against **Mary Alice Graham, Eastman, Ga.**

CHARGE: Between 3–11–59 and 4–23–59, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–3–60. $500 fine and probation for 2 years.

6285. (F.D.C. No. 44277. S. No. 75–776 P.)

INFORMATION FILED: 3–15–60, E. Dist. Mo., against **Fleek A. Pippin, t/a Pleasant View Court and Cafe and Service Station, Arnold, Mo.**

CHARGE: On 9–16–59, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–7–60. Fine of $500, plus costs, and sentence of 10 days in jail.

6286. (F.D.C. No. 44320. S. Nos. 80–351/60 P, 80–381/2 P.)

INFORMATION FILED: 10–3–60, N. Dist. Ohio, against **Turnpike Clothing Center (a partnership), North Lima, Ohio; Edward C. Coler and Paul C. Schmidt, Jr. (partners); and Wayne Morris and Calvin Morris (employees).**

CHARGE: Between 9–10–59 and 10–12–59, *amphetamine sulfate tablets* were dispensed 12 times without a prescription.

PLEA: Guilty by the partnership, Coler, and Schmidt to all 12 counts; and by Wayne Morris and Calvin Morris to 3 counts each.

DISPOSITION: 10–21–60. Partnership—$300 fine; Coler and Schmidt—each fined $300 and sentenced to 6 months imprisonment which sentence was suspended; Wayne Morris and Calvin Morris—$75 fine each.

6287. (F.D.C. No. 44300. S. Nos. 79–661/4 P.)

INFORMATION FILED: 8–31–60, N. Dist. Ind., against **Edward Sparkowitz, Walkerton, Ind.**

CHARGE: Between 7–21–59 and 8–9–59, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–24–60. $1,200 fine, plus costs, sentence of 6 months in jail suspended, and probation for 1 year.

6288. (F.D.C. No. 43687. S. Nos. 71–905 M, 13–402/3 P.)

INFORMATION FILED: 4–21–60, N. Dist. Ill., against **Hubert V. Prunty, Chicago, Ill.**

CHARGE: Between 12–28–56 and 7–29–58, *dextro-amphetamine sulfate capsules* were dispensed twice without a prescription and *Tuinal capsules* were dispensed once without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–14–60. 2 years probation.

6289. (F.D.C. No. 39835. S. Nos. 14–585 M, 14–587/8 M, 14–591 M, 43–428 M, 43–578 M.)

INFORMATION FILED: 2–28–57, E. Dist. Mo., against **Marvin Roth, St. Louis, Mo.**

CHARGE: Between 9–29–56 and 2–1–57, *dextro-amphetamine sulfate tablets* and *dextro-amphetamine sulfate timed disintegration capsules* were each dispensed 2 times without a prescription, and *dextro-amphetamine sulfate tablets* were dispensed twice upon request for prescription refills without authorization from the prescriber, in violation of the Federal Food, Drug, and Cosmetic Act.

The information alleged also, in 2 counts, that the defendant, between 1–22–57 and 1–25–57, unlawfully sold *tincture opium camphorated (paregoric)*, in violation of the laws relating to the sale of narcotics, 26 U.S.C. 4705(a).

PLEA: Not guilty.

DISPOSITION: On 10–16–57, the defendant filed the following motions which were overruled by the court on 12–31–57:

(a) Motion to require production of documentary evidence and other objects in response to subpoena before trial;

(b) Motion for discovery and inspection; and

(c) Motion for production and inspection of statements and reports of Government witnesses.

On 7–22–58, the case came on to trial before the court without a jury and, on 7–24–58, the court found the defendant guilty. Thereafter, the defendant's motion for new trial was overruled. On 1–8–59, the defendant was sentenced to 8 years imprisonment on each of counts 1 and 2 of the information involving the sale of narcotics, the sentence on count 2 to run concurrently with the sentence on count 1. The defendant was also sentenced to 1 year imprisonment on each of the 6 counts involving violation of the Federal Food, Drug, and Cosmetic Act, the sentences on such counts to run currently with the sentence on count 1.

Subsequently, the defendant appealed to the United States Court of Appeals for the 8th Circuit. On 10–8–59, the court of appeals handed down the following opinion (270 F. 2d 655):

GARDNER, *Circuit Judge:* "This case was commenced by the filing of an Information charging appellant Marvin Roth, a registered pharmacist, with the unlawful sale of drugs. The Information contained eight counts. Counts One and Two of the Information charged illegal sales of tincture opium camphorated, or paregoric, in violation of Section 4705(a), Title 26, United States Code, while Counts Three to Eight, inclusive, of the Information charged illegal sales of dextro amphetamine sulphate tablets, in violation of Section 331(k), Title 21, United States Code. In the course of this opinion we shall refer to appellant as defendant. Defendant relied solely upon the defense of entrapment.

"Counts One and Two charged the unlawful sale of paregoric, which contains a narcotic and hence such a sale constitutes a felony in violation of Section 4705(a), Title 26, United States Code. The sales charged in Counts Three to Eight, inclusive, constituted misdemeanors violative of Section 331(k), Title 21, United States Code. Defendant duly waived the right of jury trial and, with the consent of the United States Attorney and the court, the cause was tried to the court without a jury. The court was therefore performing the function of court and jury.

"It is conceded by the defendant that he committed the offenses as charged in the Information, but contends that he was entrapped into so doing by agents of the Government, and that the evidence was of such a character that the Court should have sustained his motion for judgment of acquittal interposed at the close of all the testimony, on the ground that the evidence proved entrapment as a matter of law. The court denied defendant's motion for judgment of acquittal and found him guilty on all counts. As the Government was the prevailing party, we must view the evidence in a light most favorable to the Government. We must assume that all conflicts in the evidence were resolved in favor of the prevailing party and it is entitled to the benefit of all such favorable inferences as may reasonably be drawn from the facts proven, and if, when so viewed, the evidence is such that different conclusions might reasonably be drawn therefrom, a question of fact, and not a question of law, was presented. We turn to an examination of the evidence, viewing it in a light most favorable to the Government.

"As the transactions described in Counts Three to Seven, inclusive, occurred before those described in Counts One and Two, we shall consider them first.

"The evidence produced at the trial by the Government was substantially as follows. In support of the charge contained in Count Three of the Information the evidence shows that on September 29, 1956, Mr. William Boyle, an

inspector with the Food and Drug Administration, drove into a filling station operated by one Charles Gibson, in a truck tractor which had been rented for the purpose. He was dressed in work clothes and had the appearance of a truck driver. His purpose was to conduct an investigation as to whether drugs were being illegally sold at this location. If they were, he was to endeavor to obtain evidence for a conviction of the guilty parties. Mr. Boyle spoke to Mr. Gibson, saying that he wanted some aspirin to keep him awake. Mr. Gibson then called the defendant, Marvin Roth, at his home in University City. He used the number defendant had previously given where defendant said he could be reached if he ever had any call for 'bennies.' Gibson testified that he told defendant that a trucker was on the lot who wanted some 'bennies.' This term was subsequently explained as one which truck drivers and others use when referring to dextro amphetamine tablets. Defendant asked Gibson how many the trucker wanted, as it must be worth his while to come over. Gibson mentioned five hundred or a thousand tablets. Defendant said that he would come over, but that it would take a little while as he had some distance to travel.

"Boyle waited on the filling station lot and defendant arrived in thirty to forty-five minutes. Defendant was then introduced to Boyle and he asked Boyle for some identification to show that he was a truck driver. Boyle refused to identify himself, but defendant observed that Boyle's left arm was sunburned, and said that Boyle must be a truck driver. Defendant held two bottles in his hands while this conversation was in progress. He then gave them to Boyle in exchange for fifty dollars. Boyle testified that each bottle contained a thousand dextro amphetamine tablets. Boyle testified that this was the substance of his entire conversation with defendant prior to the sale.

"On Count Four the evidence shows that on October 10, 1956, Inspector Joseph Gebhart of the Food and Drug Administration obtained a prescription for fifty dextro amphetamine tablets from Dr. Bernard Flotte, a physician, in the name of Dick McCoy. McCoy was a fictitious name, which fact was known to the doctor issuing the prescription. Gebhart took the prescription to the Joseph Drug Store in St. Louis on the same date and had it filled. The charge was $2.50. The prescription called for the consumption of two pills per day by the patient and it was not to be refilled.

"On December 29, 1956, Inspector Leo Cramer of the Food and Drug Administration went to the Joseph Drug Store and gave a piece of paper with the prescription number on it which had previously been given by Gebhart to the clerk and defendant refilled the prescription. He did not obtain permission from the doctor to do so. On Cross-examination defendant admitted this and also that he had no conversation with Cramer prior to the refill.

"After receiving the tablets, Inspector Cramer asked defendant if he could sell him some metandren tablets. Defendant said that he 'should not' do so as it was a prescription item. Cramer did not press him further, merely saying that he would try to get a prescription.

"In support of Counts Five and Six, the Government's evidence was to the effect that on January 8, 1957, Inspector Cramer again went to the drug store and asked to have the McCoy prescription filled. Defendant did so, again without attempting to contact the doctor who issued it. Defendant admitted this. After obtaining the tablets, Cramer asked defendant if they would be cheaper if purchased in amounts of one hundred. Defendant said that they would not be much cheaper. Cramer then said that his son-in-law, McCoy, traveled down through Rolla on a truck route and could get rid of a lot of them. Defendant said he should buy them in larger quantities. Cramer asked where they could be purchased, and defendant said that he could provide them. When Cramer asked how long it would take to get them, defendant said he had them outside in his car. Defendant then took Cramer to his car and sold him a bottle with a thousand dextro amphetamine tablets, for $30.00.

"As to Count Seven, the Government proved that on the evening of January 10, 1957, Cramer called defendant on the telephone at the Joseph Drug Store. In this conversation Cramer arranged to buy a thousand dextro amphetamine tablets and a hundred metandren tablets. They arranged to meet but did not do so until a later time.

"On January 15, 1957, Cramer called defendant a second time at Joseph Drug. This time he asked if defendant knew about dextro amphetamine tablets that were slow in disintegrating in the system after being taken. Defendant said that Cramer meant spansules and that he had them in his car. He said that if Cramer would come right over to the store he could get them. Cramer ordered a hundred spansules and arranged to pick them up the next day.

"During this telephone conversation, Inspector Cramer said that McCoy had asked about obtaining some 'PG'. This term was subsequently explained as meaning paregoric or tincture opium camphorated, a drug containing narcotics. Cramer continued the conversation by saying that he did not want to have anything to do with paregoric. That he did not want to take a chance. Defendant said, 'I know what you mean.' 'You can get two to three' years for selling it. Cramer then said that he 'was afraid of it; it was not worth the risk.' Cramer said that he would bring McCoy down if defendant wanted to take a chance. Cramer said that McCoy had been paying $45 or $50 a gallon. Defendant then said that he could get it for less than $45. Defendant further said that paregoric was dynamite and that it meant the 'Feds.' He said that tablets were not so bad but he did not want to take a chance on 'PG.'

"On January 16, 1957, Cramer met defendant outside of Nash's Drug Store, 1601 South Jefferson Avenue, St. Louis, Missouri, pursuant to prior agreement. Defendant then gave Cramer a bottle of spansules for which he received $9.00.

"As has been observed, all these transactions resulting in sales violative of the law transpired before the sales described in Counts One and Two of the Information. In making these sales defendant was certainly not entrapped. The Government agents did nothing to implant in his mind the disposition to commit these offenses in order to prosecute, nor did they incite, induce, instigate or lure the defendant to commit these offenses which he would not otherwise have committed, and it is well settled that the mere fact that officers of the Government afford an opportunity to commit the offense charged does not constitute entrapment. *Sorrells* v. *United States*, 287 U.S. 435; *Sherman* v. *United States*, 356 U.S. 369; *Masciale* v. *United States*, 356 U.S. 386; *Butts* v. *United States*, 8 Cir., 273 Fed. 35; *Marbs et al.* v. *United States*, 8 Cir., 250 F. 2d 514. In *Sherman* v. *United States*, supra, it is said:

> * * * the fact that government agents 'merely afford opportunities or facilities for the commission of the offense does not' constitute entrapment. Entrapment occurs only when the criminal conduct was 'the product of the creative activity' of law-enforcement officials. * * * To determine whether entrapment has been established, a line must be drawn between the trap for the unwary innocent and the trap for the unwary criminal.

"We shall now consider the evidence which it is claimed by the Government sustains the conviction of defendant on Counts One and Two. In considering this evidence it must be borne in mind that the defendant had confessedly already committed the offenses charged in Counts Three, Four, Five, Six and Seven of the Information, and these, we think, were similar offenses. He could not be characterized as an unwary innocent. In fact, in connection with the transaction described in Count Seven, defendant had a conversation with a Government agent with reference to a possible sale of paregoric which was the subject of sale described in Counts One and Two. In support of Count One the Government's witness Witt testified in substance that on January 21, 1957, he met the defendant in the 1600 block of South Jefferson at the rear of the Nash Drug Store, Inspector Cramer being also present. Cramer and he had been waiting there for defendant. When defendant drove up and parked his car Cramer and he got out of their car and walked to the rear of the drug store where they met defendant. Cramer and defendant had a conversation and then Cramer introduced Witt as Dick. Defendant turned to Witt and asked, 'What do you want?' The witness told him he wanted some paregoric. Defendant asked Witt what he would pay for it and he told him he was looking for the best deal that he could get. Defendant then told Witt that he knew he had been paying forty-five and fifty dollars a gallon and offered to sell it to him for forty dollars. Witt asked defendant if he would give a better price on a larger quantity. Defendant told Witt that he would

sell him two gallons for seventy-five dollars and stated, 'I will meet you at Eighteenth and Lafayette at ten minutes to five tomorrow,' which was Tuesday. Defendant then walked on and entered the store, and Inspectors Cramer and Witt left the vicinity. Witt next met defendant the following evening at Eighteenth and Lafayette at 5:20 P.M. Defendant on seeing Witt said immediately, 'Have you got anything with your name on it?' Witt told defendant, 'I don't know anything about you, you don't know anything about me. Let's keep it that way.' Defendant agreed that this was a good idea. Witt asked if he had his merchandise, and defendant said, 'Yes, it is in the car.' Defendant then directed that Witt drive his automobile from the corner and park it in the rear of defendant's automobile to transfer the packages. Witt did this and again met defendant on the sidewalk. Witt asked him where the PG was, and defendant stated that it was on the floor in the front of the car, meaning his car. Witt asked defendant if he wanted the money now and he said 'No, leave it on the front seat,' so Witt opened the car door, and sat down on the front seat and counted out seventy-five dollars and as he started to pick up the packages he noticed that they were not labeled as paregoric. He asked defendant, 'Is this paregoric? It is not labeled and I don't want to get the wrong stuff,' and he pointed out the initial 'P' which was printed on the gallon carton, and stated, 'That stands for paregoric.' Witt then took the two cartons and walked back to the Government car and placed them in the car and met defendant again, and defendant said, 'You know, we have got to be careful about this, the Government would be interested.' Defendant then asked when Witt wanted an additional supply and was told either this week or next, and defendant asked how much he could handle and Witt said five or ten gallons. This testimony was corroborated by the witness Cramer.

"In support of the Second count the testimony of Government witnesses was to the effect that on January 25, 1957, defendant and Witt met in Forest Park as previously agreed and defendant sold five gallons of paregoric to Witt for one hundred seventy-five dollars.

"The sale charged in Count One was consummated, as has heretofore been observed, after the sales charged in Counts Three, Four, Five, Six, and Seven, all of which were violative of the law and made without any semblance of persuasion. The only words indicating that defendant was reluctant to sell paregoric were those mentioned in connection with sales described in Counts Four to Seven and it is worthy of note that it was the Government agent who first indicated a reluctance to be involved in a purchase of paregoric because of the penalties involved. The defendant at that time simply agreed with the suggestion made by the Government agent. He showed no reluctance, nor was there any persuasion involved when the actual transactions involving the sales described in Counts One and Two took place. True, the defendant testified to some protests but they apparently occurred during the transactions involved in Counts Four to Seven and the court manifestly credited the testimony of the Government witnesses. They gave their version of the transaction, the defendant gave his, and the court as the trier of the facts was the judge of the credibility of the witnesses and resolved all doubts in favor of the Government.

"Defendant cites and relies upon a number of decisions holding that the trial court erred in holding as a matter of law that there had been no entrapment. These authorities in effect hold that the question of entrapment was one of fact to be determined by the jury, and not one of law. In the instant case the defendant is contending that the question of entrapment was one of law. We cannot agree. In principle the cases cited by defendant support the Government's contention in the instant case, to-wit; that the question of whether or not defendant was entrapped was, under the evidence in this case, a question of fact. The fact that the case was tried to the court without a jury cannot change the applicable rule. We conclude that the court was warranted in finding as a fact that there was no entrapment in this case.

"The judgment is therefore affirmed."

Thereafter, the defendant filed a petition for a writ of certiorari with the United States Supreme Court which was denied on 1–11–60 (361 U.S. 931).

6290. (F.D.C. No. 43715. S. Nos. 38–131/2 P.)

INFORMATION FILED: 2–9–60, E. Dist. Mo., against **Preston Rutledge, Advance, Mo.**

CHARGE: On 3–16–59, *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–10–60. $500 fine, plus costs.

6291. (F.D.C. No. 43725. S. Nos. 48–014 P, 48–019/20 P, 63–961/3 P, 63–965/6 P, 64–065 P, 64–068 P, 64–070 P.)

INFORMATION FILED: 4–4–60, Dist. Mass., against **Glina's Pharmacy, Inc., and Max M. Wantman (president and pharmacist), Cambridge, Mass.**

CHARGE: Between 6–4–59 and 7–22–59, *dextro-amphetamine sulfate tablets* and *amphetamine sulfate tablets* were each dispensed 4 times and *pentobarbital sodium capsules* were dispensed 3 times without a prescription.

PLEA: Guilty by both defendants.

DISPOSITION: 10–24–60. Wantman—$4,000 fine, 21 months in prison suspended, and probation for 4 years; corporation—$1,100 fine, of which $900 was suspended.

6292. (F.D.C. No. 43231. S. Nos. 19–675/6 P, 19–680 P.)

INFORMATION FILED: 9–1–59, Dist. Colo., against **Robert S. Logan, t/a Logan Drug Store No. 1, Pueblo, Colo., Kenneth L. Doren and Albert W. Keithley (pharmacists).**

CHARGE: Between 11–14–58 and 11–20–58, *dextro-amphetamine sulfate tablets, V-Cillin K tablets* and *meprobamate tablets* were each dispensed once upon requests for prescription refills without authorization from the prescriber.

PLEA: Guilty by Logan to the count involving the *dextro-amphetamine sulfate tablets;* by Doren to the counts involving *dextro-amphetamine sulfate tablets* and *V-Cillin K tablets;* and by Keithley to the count involving *meprobamate tablets.*

DISPOSITION: 9–23–60. Logan—$500 fine; Doren—$200 fine; Keithley—$200 fine.

6293. (F.D.C. No. 44623. S. No. 5–849 P.)

INFORMATION FILED: 10–14–60, W. Dist. Va., against **Ray E. Harrington (a partner in Glenvar Texaco Station), Salem, Va.**

CHARGE: On 9–17–59, *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–14–60. $500 fine and probation for 2 years.

6294. (F.D.C. No. 44343. S. Nos. 74–949 P, 97–517 P.)

INFORMATION FILED: 7–6–60, N. Dist. Ill., against **Victor N. La Marre (a medical doctor), Chicago Heights, Ill.**

CHARGE: Between 10–21–59 and 12–9–59, *dextro-amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Nolo contendere.

DISPOSITION: 11–22–60. Probation for 2 years.

6295. (F.D.C. No. 42474. S. Nos. 43–401 P, 43–616 P, 43–673/4 P, 43–676/8 P.)

INFORMATION FILED: 8–17–59, Dist. Colo., against **Adolphus Adams, t/a Adams Drug, Pueblo, Colo., and George J. Lohmiller (pharmacist).**

CHARGE: Between 6–25–58 and 12–9–58, *meprobamate tablets* were dispensed 3 times, and *Terramycin liquid*, *Terramycin powder*, *penicillin V capsules*, and *penicillin V potassium tablets* were each dispensed once upon requests for prescription refills without authorization by the prescribers.

PLEA: Guilty by Lohmiller to 1 count each involving *meprobamate tablets*, *Terramycin powder*, and *penicillin V capsules;* and by Adams to 1 count each involving *Terramycin liquid* and *penicillin V potassium tablets* and to 2 counts involving *meprobamate tablets*.

DISPOSITION: 10–9–59. Lohmiller was fined $375 and placed on probation for 1 year; on 10–28–59, an order was entered releasing him from probation.

9–26–60. Adams was fined $575 and placed on probation for 1 year.

6296. (F.D.C. No. 44324. S. No. 5–913 P.)

INFORMATION FILED: 7–25–60, E. Dist. N.C., against **William H. Stanton, t/a Stanton's Pharmacy, New Bern, N.C.**

CHARGE: On 3–17–59, *Equanil tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 10–31–60. $250 fine and probation for 2 years.

6297. (F.D.C. No. 42493. S. Nos. 46–416/8 P.)

INFORMATION FILED: 7–26–60, N. Dist. Miss., against **Harvey Cobb, t/a Cobb's 6–51 Truck Stop, Batesville, Miss.**

CHARGE: Between 10–8–59 and 10–24–59, *desoxyephedrine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–7–60. $300 fine and probation for 2 years.

6298. (F.D.C. No. 43228. S. Nos. 31–878 P, 32–129/31 P, 57–681 P.)

INFORMATION FILED: 6–15–60, S. Dist. N.Y., against **Joseph Sacks Pharmacy, Inc., New York, N.Y., and Joseph Sacks (president).**

CHARGE: Between 11–13–58 and 12–5–58, *Dexedrine Sulfate tablets* were dispensed 3 times without a prescription and *Tuinal capsules* were dispensed twice upon requests for a prescription refill without authorization from the prescriber.

PLEA: Guilty by both defendants.

DISPOSITION: 11–3–60. Corporation—$1 fine; individual—$2,000 fine, 6 months imprisonment on each count suspended, and probation for 2 years.

6299. (F.D.C. No. 42399. S. Nos. 36–380 P, 36–398 P, 37–363 P.)

INFORMATION FILED: 6–30–60, E. Dist. Mo., against **Mack C. Finch, t/a Finch Drug Store, Doniphan, Mo., and Waymon K. Wiggins (employee).**

CHARGE: Between 2–18–58 and 3–5–58, *pentobarbital sodium capsules* were dispensed once upon request for a prescription refill without authorization from the prescriber, and *Equanil tablets* and *digitalis tablets* were each dispensed once without a prescription.

PLEA: Guilty by Finch to all counts; and by Wiggins to the count involving *Equanil tablets*.

DISPOSITION: 10–10–60. Finch—$500 fine; Wiggins—$100 fine.

6300. (F.D.C. No. 43678. S. Nos. 5–851/4 P, 5–856/7 P.)

INFORMATION FILED: 12–11–59, E. Dist. N.C., against **Ralph H. Ashworth, t/a Ashworth Rexall Drugs, Cary, N.C., and William C. Griffin (pharmacist).**

CHARGE: Between 3–31–59 and 4–29–59, *Darvon Compound capsules* were dispensed 3 times, *pentobarbital sodium capsules* were dispensed twice, and *meprobamate tablets* were dispensed once without a prescription.

PLEA: Guilty by Ashworth to one count involving *meprobamate tablets;* and by Griffin to the other counts of the information.

DISPOSITION: 10–3–60. Ashworth—$100 fine; Griffin—$300 fine. Both defendants were placed on probation for 2 years.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6289) Prosecution contested. Contains opinion of the court.
[2] (6281) Injunction issued.

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U.S. GOVERNMENT PRINTING OFFICE: 1961

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D.D.N.J., F.D.C. 6341-6360

Issued May 1961

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6341-6360

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs which are required at time of interstate shipment to bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription," and which were dispensed after such shipment without a prescription or by refilling a prescription without authorization. This dispensing was contrary to Section 503(b)(1), and thereby resulted in the dispensed drugs being misbranded while held for sale.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *May 22, 1961.*

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592549—61

VIOLATIVE SALES OF PRESCRIPTION DRUGS

6341. (F.D.C. No. 42480. S. No. 66–005 P.)

INFORMATION FILED: 10–5–59, Dist. Conn., against **Charles W. Christiansen, alias Charlie Benjamin, at Stamford, Conn.**

CHARGE: On 8–27–59, *amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 12–9–59. $500 fine.

6342. (F.D.C. No. 42483. S. Nos. 46–607/8 P.)

INFORMATION FILED: 5–9–60, N. Dist. Ala., against **Medical Specialties Corp., South Birmingham, Ala., Ernest L. Wade (secretary-treasurer of the corporation), and Charles F. Rattray, t/a Sutherlin Drug Store, Gadsden, Ala.**

CHARGE: The information alleged in count 1 that the defendants did, on 9–1–58 and continuing thereafter to 12–14–59, conspire, combine, confederate, and agree together and with divers other unknown persons to commit offenses against the United States, namely, to unlawfully dispense articles of drugs consisting of unknown quantities of *amphetamine sulfate tablets* and *amphetamine sulfate capsules* while such drugs were held for sale after shipment in interstate commerce, thereby causing such drugs to become misbranded.

It was alleged further as a part of the conspiracy that the defendants would purchase large amounts of amphetamine sulfate drugs which had been shipped in interstate commerce into the State of Alabama; that the defendants would sell and dispense such drugs in large quantities to customers without a physician's prescription; and that the defendants would deliver such drugs to customers in unlabeled containers.

It was alleged further that in furtherance of the conspiracy and to effect the objects thereof, the defendants did commit the following overt acts:

(1) between 9–1–58 and 12–14–59, Medical Specialties Corp., and Ernest Wade caused to be ordered and purchased large supplies of *amphetamine sulfate tablets* and *amphetamine sulfate capsules* from various manufacturers in Tennessee, Pennsylvania, and Texas;

(2) pursuant to such orders, large supplies of *amphetamine sulfate tablets* and *amphetamine sulfate capsules* were shipped from Tennessee, Pennsylvania, and Texas into Alabama consigned to the Medical Specialties Corp.;

(3) on 11–11–59, Ernest Wade unlawfully dispensed a number of *amphetamine sulfate tablets* to a Government agent, known to Ernest Wade as a truck driver, without a prescription therefor;

(4) between 11–2–59 and 12–14–59, Ernest Wade referred the above-mentioned Government agent to Charles Rattray for the purpose of making further purchases of amphetamine sulfate drugs;

(5) on 11–25–59, Charles Rattray unlawfully dispensed a number of *amphetamine sulfate tablets* to a Government agent, known to him as a truck driver, without a prescription therefor;

(6) between 11–2–59 and 12–14–59, conversations were had between a Government agent, posing as a truck driver, and Ernest Wade, and between the same Government agent and Charles Rattray concerning the making of arrangements for the purchase, by the Government agent, of ½ million *amphetamine sulfate tablets* and *amphetamine sulfate capsules;*

(7) between 9–1–58 and 12–14–59, Ernest Wade caused a number of invoices to be made reflecting a number of sales by Medical Specialties Corp. of large amounts of *amphetamine sulfate tablets* and *amphetamine sulfate capsules* to authorized retail outlets such as medical doctors and drug stores, which invoices were false in that the consignees named in the invoices did not purchase or receive the large amounts of *amphetamine sulfate tablets* and *amphetamine sulfate capsules* indicated on the invoices.

The information further alleged in two other counts, with respect to *amphetamine sulfate tablets* which had been shipped in interstate commerce, that the defendants, on 11–11–59, caused a number of such tablets to be dispensed at Birmingham, Ala., without a prescription and that the defendants, on 11–25–59, caused a number of such tablets to be dispensed at Gadsden, Ala., without a prescription.

PLEA: Nolo contendere by the corporation; and guilty by the individuals.

DISPOSITION: 6–3–60. Medical Specialties Corp., and Ernest Wade were each fined $500; and Charles Rattray was fined $150.

6343. (F.D.C. No. 43260. S. Nos. 1–240 P, 56–319 P.)

INDICTMENT RETURNED: 11–3–59, N. Dist, Ga., against **John Hansford Oakes, Gainesville, Ga.**

CHARGE: On 12–17–58, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 6–23–60. Sentence of 6 months in jail.

6344. (F.D.C. No. 43243. S. Nos. 2–123 P, 44–114 P.)

INDICTMENT RETURNED: 11–3–59, N. Dist. Ga., against **Jay Everrett Guffey, Cumming, Ga.**

CHARGE: On 10–30–58, *amphetamine sulfate tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 7–14–60. Sentence of 12 months in jail.

6345. (F.D.C. No. 44633. S. Nos. 57–205 P, 57–218 P, 72–409 P, 72–507 P.)

INFORMATION FILED: 7–13–60, S. Dist. Ga., against **Wilbert Roller, t/a DeSoto Truck Stop, Chatham County, Savannah, Ga., and Edmund I. Honeycutt (an employee).**

CHARGE: Between 9–22–59 and 10–20–59, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Nolo contendere by Honeycutt to 2 counts and by Roller to 2 counts.

DISPOSITION: 8–1–60. Roller—$750 fine and probation for 2 years; Honeycutt—$350 fine and probation for 2 years.

6346. (F.D.C. No. 44628. S. Nos. 80–451/3 P.)

INFORMATION FILED: 6–30–60, N. Dist. Ind., against **Ruth Lambright, t/a Economy Lunch, Ligonier, Ind.**

CHARGE: Between 10–15–59 and 10–21–59, *amphetamine sulfate tablets* were dispensed 3 times without a prescription.

PLEA: Guilty.

DISPOSITION: 9–8–60. 6 months imprisonment on each count suspended, and probation for 2 years.

6347. (F.D.C. No. 44648. S. Nos. 29–318 P, 73–599 P, 73–606 P, 73–619/20 P.)

INFORMATION FILED: 8–15–60, N. Dist. Miss., against **Pauline Harkey Sergerson Abercrombie, t/a Polly's Truck Stop, Columbus, Miss.**

CHARGE: Between 6–11–59 and 9–7–59, *amphetamine sulfate tablets* were dispensed 3 times and *desoxyephedrine hydrochloride* tablets were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–22–60. $300 fine and probation for 2 years.

6348. (F.D.C. No. 44297. S. Nos. 80–371/6 P.)

INFORMATION FILED: 5–26–60, N. Dist. Ohio, against **Alfred J. Ruocchio, t/a Cloverleaf Truck Stop, Streetsboro, Ohio.**

CHARGE: Between 9–10–59 and 10–10–59, *amphetamine sulfate tablets* were dispensed 6 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–7–60. $500 fine and probation for 5 years.

6349. (F.D.C. No. 44314. S. Nos. 80–341/4 P.)

INFORMATION FILED: 5–26–60, N. Dist. Ohio, against **Monte Fortnoff (an employee of a truck stop at Streetsboro, Ohio).**

CHARGE: Between 9–3–59 and 9–15–59, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 10–7–60. $500 fine and probation for 5 years.

6350. (F.D.C. No. 44631. S. Nos. 59–652/3 P, 59–655/6 P.)

INFORMATION FILED: 9–3–60, W. Dist. Va., against **Douglas E. Adams, Charles W. Coe, and Roylence M. Link, Draper, Va.**

CHARGE: Between 8–27–59 and 9–18–59, *amphetamine sulfate tablets* (counts 1 and 3) and *dextro-amphetamine sulfate tablets* (counts 2 and 4) were each dispensed twice without a prescription.

PLEA: Guilty by Adams to counts 1 and 2; by Coe to count 3; and by Link to count 4.

DISPOSITION: 11–14–60 and 11–15–60. Each of the defendants was fined $500 and placed on probation for 2 years.

6351. (F.D.C. No. 44641. S. Nos. 57–213 P, 57–221 P, 71–944 P, 72–307 P.)

INDICTMENT RETURNED: 9–9–60, M. Dist. Ga., against **Johnnie Franklin Giles (an employee of a truck stop at Moultrie, Ga.).**

CHARGE: Between 10–6–59 and 10–26–59, *amphetamine sulfate tablets* and *desoxyephedrine hydrochloride tablets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 11–22–60. Probation for 2 years.

6352. (F.D.C. No. 43683. S. Nos. 47–652 P, 47–659 P, 48–164 P, 48–165 P.)

INFORMATION FILED: 12–4–59, Dist. Mass., against **Joseph Flitter, t/a Family Pharmacy, Roxbury (Boston), Mass.**

CHARGE: Between 12–31–58 and 3–16–59, *amphetamine sulfate tablets* were dispensed 4 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–28–60. $1,000 fine, sentence of 1 year in prison suspended, and probation for 2 years.

6353. (F.D.C. No. 44637. S. Nos. 46–401/6 P.)

INFORMATION FILED: 7–26–60, N. Dist. Miss., against **Ramage Bros. Truck Stop (a partnership), Tunica, Miss., and James H. Ramage (a partner).**

CHARGE: Between 8–31–59 and 9–8–59, *amphetamine sulfate tablets* were dispensed 5 times without a prescription.

PLEA: Guilty.

DISPOSITION: 11–7–60. Partnership—$500 fine; individual—probation for 2 years.

6354. (F.D.C. No. 37247. S. Nos. 82–586 L, 88–390 L, 88–394 L, 88–397 L.)

INFORMATION FILED: 12–11–57, W. Dist. N.Y., against **James J. Billings, Rochester, N.Y.**

CHARGE: Between 4–20–54 and 6–3–54, *pentobarbital sodium capsules* were dispensed once and *sulfisoxazole tablets* were dispensed 3 times upon requests for prescription refills without authorization from a prescriber.

PLEA: Nolo contendere.

DISPOSITION: 9–27–60. $200 fine, of which $150 was remitted.

6355. (F.D.C. No. 44652. S. Nos. 55–823 P, 55–828 P, 55–830 P, 97–589 P.)

INFORMATION FILED: 9–1–60, W. Dist. Okla., against **John N. Breeding, Oklahoma City, Okla.**

CHARGE: Between 12–13–59 and 1–12–60, *pentobarbital sodium capsules* were dispensed 4 times upon requests for prescription refills without authorization from a prescriber.

PLEA: Nolo contendere.

DISPOSITION: 11–14–60. Probation for 3 years.

6356. (F.D.C. No. 42461. S. Nos. 73–255 M, 73–436 M, 18–754 P.)

INFORMATION FILED: 4–12–60, N. Dist. Tex., against **Alfred R. Collins, t/a Collins Bros. Walgreen Agency Drug, Big Spring, Tex.**

CHARGE: Between 10–24–57 and 4–15–58, *penicillin tablets* were dispensed twice and *dextro-amphetamine sulfate tablets* were dispensed once without a prescription.

PLEA: Guilty.

DISPOSITION: 11–8–60. $1,000 fine, 1 year imprisonment suspended, and probation for 1 year.

6357. (F.D.C. No. 44310. S. No. 56–800 P.)

INFORMATION FILED: 6–1–60, S. Dist. Fla., against **Ammerman, Inc., t/a Trail Drugs, Miami, Fla., and Martin Meyer Ammerman (president and pharmacist).**

CHARGE: On 5–31–59, *Miltown tablets* were dispensed once without a prescription.

PLEA: Guilty by both defendants.

DISPOSITION: 11–18–60. Corporation—$1,000 fine; individual—$1,000 fine and probation for 6 months.

6358. (F.D.C. No. 44656. S. Nos. 71–678/9 P.)

INFORMATION FILED: 9–1–60, N. Dist. Ga., against **Georgia Drug Store, Inc., Atlanta, Ga., and Lila Callahan Gross (president).**

CHARGE: Between 11–5–59 and 11–17–59, *Miltown tablets* were dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 9–27–60. Corporation fined $300; individual placed on probation for 2 years.

6359. (F.D.C. No. 44643. S. Nos. 42–821/2 P, 42–824/5 P, 42–827 P, 71–282/3 P.)

INFORMATION FILED: 8–15–60, S. Dist. Ind., against **C. Miles Wickham, t/a New Palestine Drugs, New Palestine, Ind.**

CHARGE: Between 12–17–59 and 1–26–60, *meprobamate tablets* were dispensed once, and *dextro-amphetamine sulfate capsules, dextro-amphetamine sulfate tablets,* and *penicillin G potassium tablets* were each dispensed twice without a prescription.

PLEA: Guilty.

DISPOSITION: 10–28–60. $700 fine, plus costs, 60 days in jail on each count suspended, and probation for 2 years.

6360. (F.D.C. No. 42485. S. Nos. 70–946 P, 70–948 P, 70–952 P.)

INFORMATION FILED: 3–2–60, S. Dist. Ind., against **Chester Menk, t/a Shifting Sands Truck Stop, Oaktown, Ind., and Elmer Menk (an employee).**

CHARGE: Between 1–19–60 and 2–3–60, *desoxyephedrine hydrochloride tablets* were dispensed 3 times without a prescription.

PLEA: Guilty by Chester Menk to all counts and by Elmer Menk to 2 counts.

DISPOSITION: 6–3–60. Chester Menk—$1,000 fine, plus costs, and 2 years in prison. 6–15–60. Elmer Menk—1 year in prison.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U.S. GOVERNMENT PRINTING OFFICE: 1961

D.D.N.J., F.D.C. 6361–6380 Issued June 1961

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6361–6380

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default, by consent, or by summary judgment and in which, in one case, a decree of condemnation and permanent injunction was entered by consent, and (2) a criminal proceeding terminated upon a plea of guilty. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *June 8, 1961.*

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*For drug in violation of prescription labeling requirements, see No. 6366; an imitation of another drug, No. 6367; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6367, 6368; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6367, 6376.

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6361–6380

Adulteration, Section 501(a)(1), the article consisted in part of a filthy substance; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(i)(2), the article was an imitation of another drug; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling; Section 502(l), the article was composed wholly or in part of penicillin, or chloramphenicol, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

DEVICE FOR HUMAN USE

6361. Thiede's head harness. (F.D.C. No. 44757. S. No. 18–041 R.)

QUANTITY: 2 devices at Billings, Mont.

SHIPPED: About March 1959, from Idaho Falls, Idaho, by Thiede Enterprise, Inc.

LABEL IN PART: "Thiede's Stretch to Health Head Harness Company, Idaho Falls, Idaho."

ACCOMPANYING LABELING: Pamphlet entitled "A Simple Improved Method for Vertebral Traction."

RESULTS OF INVESTIGATION: The article consisted of a head harness and accessories intended for supporting the head while the rest of the body would dangle, thus pulling on the neck muscles.

LIBELED: 7–27–60, Dist. Mont.

CHARGE: 502(j)—when shipped, the article was dangerous to health when used as directed in its labeling.

DISPOSITION: 8–23–60. Default—destruction.

DRUG FOR VETERINARY USE

6362. Black Widow Smear (veterinary). (F.D.C. No. 44705. S. No. 19–184 R.)

QUANTITY: 6 16-oz. jars, 10 32-oz. jars, and 4 1-gal. jars at Artesia, N. Mex.

SHIPPED: 10–3–59, from Booker, Tex., by Brewer & Johnson.

LABEL IN PART: "Black Widow Smear A Worm Killer, Healer and Repellant. * * * Active Ingredients: Castor Oil 17.25%; Benzol 30.48%: Coal Tar Natural Oils 19.00%; Soap 12.90%; Coal Tar Phenols 6.44% * * * Manufactured & Distributed by Brewer & Johnson * * * Booker, Texas."

LIBELED: 7–5–60, Dist. N. Mex.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for pink eyes in livestock; and 502(j)—the article was dangerous to health when used in the dosage, or with the frequency or duration recommended or suggested in its labeling, namely, "Directions—For screw worms apply in and around wound. For pink eyes apply around the eyes with a brush or wooden paddle. Dehorning: Apply IN AND AROUND but DON'T FILL HORN. Castration, wire cuts, apply in and around area. Fleece worms apply in and around infected parts. Ear Ticks, use brush and apply inside of ear."

DISPOSITION: 8–8–60. Default—destruction.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6363. Delfetamine tablets. (F.D.C. No. 44683. S. Nos. 40–625/6 R.)

QUANTITY: 3 drums, containing respectively 40,900 tablets, 36,100 tablets, and 22,000 tablets, at St. Louis, Mo.

SHIPPED: 5–2–60 and 5–12–60, from Baltimore, Md. These were return shipments.

LABEL IN PART: "Delfetamine . . . 30 mg. Stedytabs Each tablet contains: *Delfetamine . . . 30 mg. Caution * * * Average Dose * * * *Registered Trademark of dl-N-methyl-beta phenylisopropylamine Hydrochloride."

LIBELED: 6–24–60, E. Dist. Mo.

CHARGE: 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 9–8–60. Default—destruction.

6364. Allergy capsules and Trim-All capsules. (F.D.C. No. 44570. S. Nos. 25–909/10 R.)

QUANTITY: 1 drum containing about 10,000 *allergy capsules* and 1 ctn. containing about 15,000 *Trim-All capsules* at N. Hollywood, Calif., in possession of Windsor Corp.

SHIPPED: 10–15–59, from Englewood, N.J., by Zenith Laboratories, Inc.

LABEL IN PART: (Drum) "Zenith Laboratories, Inc., Englewood, New Jersey 1 Carton Containing 10M T.D. Capsules Each capsule contains: Pyrilamine Maleate 30 mg. Phenylephrine HCl 15 mg. Chlorprophenpyridamine 5 mg. * * * Lot No. 923765 TO: Windsor Corporation * * * North Hollywood, Calif."; (box) "Allergy Capsules * * * Anti-Allergy (Timed Disintegrating Capsules) For use as a Decongestant in Vasomotor Rhinitis, and in the symptomatic treatment of Urticaria, Hay fever and Asthma * * * Each capsule contains * * * 45129 Windsor Corporation"; (ctn.) "Zenith Laboratories, Inc., Englewood, New Jersey 1 Carton Containing 25M T.D. Capsules Each Capsule contains: Phenylpropanolamine 60 mg. Sodium Caseinate 2 gr. Dextrose 2 gr. Ascorbic Acid 50 mg. * * * Lot No. 928095 * * * TO: Windsor

Corporation, North Hollywood, Calif."; and (box) "Trim-All An Appetite Depressant * * * Each Trim-All Timed Capsule contains: * * * Lose Weight—Look Better, Feel Better * * * Windsor Corporation * * * 18489."

RESULTS OF INVESTIGATION: The article in the drum was to be repacked into the boxes labeled "*Allergy capsules*" and the article in the carton was to be repacked into the boxes labeled "Trim-All."

LIBELED: 5–17–60, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the name of the article "*Allergy Capsules*" and the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for all allergic conditions, vasomotor rhinitis, urticaria, hay fever, and asthma; and the name of the article of "*Trim-All*" *capsules* and the labeling which accompanied such article contained false and misleading representations that the article was capable of causing all users to have a trim figure; and that such article was an appetite-depressant and would cause the user to lose weight; and 505(a)—both articles were new drugs within the meaning of the law and applications filed pursuant to the law were not effective with respect to such drugs.

DISPOSITION: 7–11–60. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

6365. Penicillin G potassium tablets. (F.D.C. No. 44053. S. No. 49–260 P.)

QUANTITY: 549 btls. at San Francisco, Calif.

SHIPPED: 11–17–59, from Hoboken, N.J., by Morse Laboratories, Inc.

LABEL IN PART: "100 Buffered Penicillin Tablets Crystalline G Potassium 200,000 Units."

RESULTS OF INVESTIGATION: The article was labeled as described above after its arrival at San Francisco, Calif.

LIBELED: 2–5–60, N. Dist. Calif.

CHARGE: 502(l)—when shipped, the article was composed wholly or in part of penicillin and was from a batch with respect to which a certificate or release had not been issued pursuant to 507, since effective exemption or supplemental certification of the batch had not been obtained.

DISPOSITION: 5–12–60. Consent—claimed by Morse Laboratories, Inc., and brought into compliance with the law.

6366. Sopamycetin chloramphenicol capsules. (F.D.C. No. 44747. S. No. 2–401 R.)

QUANTITY: 1 90-capsule btl. at Fort Lauderdale, Fla.

SHIPPED: 2–16–60, from West Palm Beach, Fla., by Medical Associates Corp., after having been imported into the United States.

LABEL IN PART: (Ctn. and btl.) "Sopamycetin Chloramphenicol Capsules * * * ets Sopar Brussels-Belgium Each capsule contains 250 mg. Chloramphenicol SUP XV Made in Belgium."

RESULTS OF INVESTIGATION: Analysis showed that the article contained the declared amount of chloramphenicol.

LIBELED: 8–3–60, S. Dist. Fla.

CHARGE: 502(f)(2)—when shipped, the labeling failed to bear the warning statement that chloramphenicol should not be used indiscriminately or for

minor infections, since certain cases of serious blood dyscrasias (aplastic anemia, thrombocytopenic purpura, granulocytopenia, and pancytopenia) have been associated with the administration of chloramphenicol, and the statement that when prolonged or intermittent administration is required, adequate blood studies should be carried out; 502(l)—the article was a drug, chloramphenicol, and was not from a batch with respect to which a certificate or release had been issued pursuant to 507, and it was not exempt from such requirements by regulations promulgated pursuant to 507; and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–14–60. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6367. Amphetamine sulfate tablets, dextro-amphetamine tablets, and Dexobarbital tablets. (F.D.C. No. 43630. S. Nos. 74–662/7 P, 74–669/70 P.)

QUANTITY: 24 1,000-tablet unlabeled btls. of amphetamine sulfate, 15 1,000-tablet labeled btls. of dextro-amphetamine sulfate tablets, and 3 1,000-tablet btls. of Dexobarbital, in possession of Robert Rubin Yablon, t/a Sharon Rexall Drugs, Chicago, Ill.

SHIPPED: Prior to 10–28–59, from outside the State of Illinois.

LIBELED: 10–30–59, N. Dist. Ill.; amended 9–23–60.

CHARGE: 502(b)(1)—while held for sale, the articles (all lots) failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; 502(b)(2)—the article (24 btls.) failed to bear an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(f)(1)—the labeling of the articles (all lots) failed to bear adequate directions for use and the articles were not exempt from such requirement since they were not to be dispensed upon prescription in accordance with Section 503(b)(1); and 502(i)(2)—the article (15 btls.) was an imitation of another drug, namely, Dexedrine Sulfate.

DISPOSITION: 11–7–60. Robert Yablon, claimant, having filed an answer denying that the articles were misbranded, and the Government having filed a motion for summary judgment on the ground that there was no genuine issue of material fact between the parties in regard to the misbranding of the articles under 502(b)(1) and (2), and the claimant having failed to make any objection to such motion, judgment of condemnation was entered and the articles were ordered destroyed.

6368. Lone Indian Herb Tonic. (F.D.C. No. 44432. S. No. 71–277 P.)

QUANTITY: Undetermined number of 8-oz. btls. at Baxter, Ky., in possession of B. Daniel Fannon, t/a Jot-Em-Down Store.

SHIPPED: The powdered aloes ingredient of the article had been shipped from Knoxville, Tenn., on an unknown date.

LABEL IN PART: "NBS Lone Indian Herb Tonic Nerve, Blood & Stomach * * * This is a mild laxative Made from the Apple Family: Bitter Apple, Orange Apple, Aloes Powders, Salicylic, Red Cherry Powders and Distilled

*See also No. 6366.

water—Contains Vitamins of the Fruit Family. Directions * * * Lone Indian Remedies, Baxter, Ky."

ACCOMPANYING LABELING: Window streamers reading in part "Lone Indian Herb Tonic Nerve—Blood and Stomach—Well known for Rheumatism and Arthritis Pain," and a number of loose bottle labels.

LIBELED: 4–15–60, E. Dist. Ky.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for constipation, liver, kidney, and bladder troubles; swelling of joints and muscles, with aches and pains of the body; a dizzy feeling of the head; no appetite; and no rest at night; 502(b)(2)—the article failed to bear a label containing an accurate statement of the quantity of contents; and 502(f)(2)—the label of the article failed to bear a warning that its use should be discontinued when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present; and that frequent or prolonged use of the article may result in dependence on laxatives.

DISPOSITION: 10–12–60. Default—destruction.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

6369. Lobelia herb. (F.D.C. No. 44612. S. Nos. 35–326/7 R.)

QUANTITY: 3 bales at New York, N.Y.

SHIPPED: 10–20–58, from Bristol, Tenn.

LIBELED: 6–22–60, S. Dist. N.Y.

CHARGE: 501(a)(1)—while held for sale, the article contained insects.

DISPOSITION: 9–12–60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6370. Folabin. (F.D.C. No. 44816. S. No. 26–563 R.)

QUANTITY: 107 cartoned vials at Los Angeles, Calif.

SHIPPED: 7–1–60, from Cedar Rapids, Iowa, by Paul Maney Laboratories, Inc., Div. of Michigan Chemical Corp.

LABEL IN PART: (Vial) "10 cc. X-558 Folabin Double Strength * * * Paul Maney Laboratories, Cedar Rapids, Iowa * * * 5863."

RESULTS OF INVESTIGATION: Examination showed that the article contained about 75 percent of the labeled amount of vitamin B_{12}.

LIBELED: 10–11–60, S. Dist. Calif.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; and 502(a)—the label statements "Each cc. Contains: Vitamin B_{12} Activity * * * Equivalent to Cyanocobalamin * * * 10 mcgm. * * * Vit. B_{12} Cryst. 50 mcgm. Total B_{12} Activity 60 mcgm." were false and misleading.

DISPOSITION: 11–2–60. Default—destruction.

6371. Contact lens wetting solution. (F.D.C. No. 44580. S. Nos. 34–771 R, 34–773 R.)

QUANTITY: 752 5-cc. vials and 72 cartoned pt. btls. at New York, N.Y.

SHIPPED: 1–11–60 and 1–26–60, from Wauconda, Ill., by Micon Laboratories.

LABEL IN PART: (Vial) "Sample UCL Wetting Solution Directions * * * Distributed by United Contact Lens Corp. 76 Madison Ave., New York 16, N.Y."; (ctn.) "W. S. Micon From Micon Labs. Wauconda, Ill."

LIBELED: On or about 5-27-60, S. Dist. N.Y.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it purported or was represented to possess, since it purported to be suitable for use in the eye and for cleaning contact lenses, whereas, it was not suitable for such uses and purposes, since it was contaminated with viable micro-organisms.

DISPOSITION: 10-13-60. Consent—destruction.

6372. **Rubber prophylactics.** (F.D.C. No. 44788. S. No. 47-171 R.)

QUANTITY: 84 gross ctns., each containing 12 boxes, each box containing 3 boxes of 3 *prophylactics*, at Detroit, Mich.

SHIPPED: 5-13-60 and 6-8-60, from New York, N.Y., by the Goodwear Rubber Co.

LABEL IN PART: (Boxes and unit wrappers) "Sultan Lubricated Prophylactics * * * Sold for the prevention of disease only mfd. by L. E. Shunk Latex Products Div. of the Akwell Corp. Akron, Ohio."

RESULTS OF INVESTIGATION: Examination showed that 1.77 percent of the article contained holes.

LIBELED: 9-2-60, E. Dist. Mich.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statements "prevention of disease" were false and misleading.

DISPOSITION: 10-6-60. Default—destruction.

6373. **Rubber prophylactics (3 seizure actions).** (F.D.C. Nos. 44490, 44506, 44729. S. Nos. 23-187 R, 23-189/91 R, 23-496/7 R.)

QUANTITY: 253 ctns., each containing 48 boxes of 3 *prophylactics* each; 69 ctns., each containing 12 boxes of 4 pkgs., each pkg. containing 3 *prophylactics;* 83 ctns., each containing 144 foil-wrapped *prophylactics;* and 47 ctns., each containing 144 boxes containing 1 *prophylactic* each, at Oklahoma City, Okla.

SHIPPED: Between 4-8-60 and 6-2-60, from Akron, Ohio, by March Rubber & Plastics Co., Inc.

LABEL IN PART: (Box) "Gladiator Transparent Thins," "Checks Deluxe Thin Prophylactics," "Gladiator Prophylactics"; (foil-wrap) "Latex Poket-Pak Prophylactic."

RESULTS OF INVESTIGATION: Examination showed that between 2 and 6 percent of the articles were defective in that they contained holes.

LIBELED: On or about 6-14-60, 6-29-60, and 7-20-60, W. Dist. Okla.

CHARGE: 501(c)—the quality of the articles fell below that which they purported and were represented to possess; and 502(a)—the label statements "Sold for Prevention of Disease Only," "Sold and Intended for Prevention of Disease Only," and "For Prevention of Disease" were false and misleading as applied to articles containing holes.

DISPOSITION: 10-5-60. Consent—claimed by March Rubber & Plastics Co., Inc., and destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

6374. S.F. vitamin tablets with phenylpropanolamine, and appetite depressant tablets. (F.D.C. No. 44674. S. Nos. 18–815/6 R.)

QUANTITY: 50,900 *S.F. vitamin tablets with phenylpropanolamine* in bulk drums, and 7 60-tablet btls. of *appetite depressant tablets*, at El Paso, Tex., in possession of Okies Drug Co., Inc.

SHIPPED: 10–29–59, from Memphis, Tenn., by Morton Pharmaceuticals, Inc.

LABEL IN PART: (Drum) "54,000 Lot #1590301 S.F. Vitamin With Phenylpropanolamine Each Tablet Contains: Phenyl Propanolamine Hydrochloride 25 mg. Thiamine Mononitrate 5 mg. Riboflavin 2 mg. Niacinamide 3.4 mg. Ascorbic Acid 10 mg. Dextrose 2 gr. Sodium Caseinate 1 gr. * * * Prepared for Okies Drug Co., Inc., El Paso, Texas;" and (btl.) "Okies Appetite Depressant Tablets."

RESULTS OF INVESTIGATION: The 7 60-tablet bottles were repacked by the dealer from the stock in the bulk drums.

LIBELED: 6–22–60, W. Dist. Tex.

CHARGE: 502(a)—when shipped and while held for sale, the labels of the article contained false and misleading representations that it was effective for weight control and as an appetite depressant; that the article would cause the user to eat less, live longer, lose weight and feel better; and that the article was a new approach to reducing.

DISPOSITION: 8–17–60. Default—destruction.

6375. Vegetable juices. (F.D.C. No. 43599. S. Nos. 63–201/3 P, 80–098/9 P.)

QUANTITY: 100 24-can cases of labeled carrot juice and 24 24-can cases of unlabeled carrot juice; 42 24-can cases of labeled celery juice and 25 24-can cases of unlabeled celery juice; and 30 24-can cases of labeled beet juice, at Detroit, Mich., in possession of Health Champions, Inc.

SHIPPED: Between 4–8–58 and 8–1–59, from Eugene, Oreg.

LABEL IN PART: (Can) "Organi-Rich Natural Oregon Carrot Juice [or "Celery Juice" or "Beet Juice"] Contents: 1 Pt. 2 Fluid Ounces. [or "12 fl. oz."] Undiluted, no salt, no color, no preservative added. Packed for: Health Champions, Inc. Detroit 5, Mich."

ACCOMPANYING LABELING: Booklets entitled "Raw Vegetable Juices," "Nature's Way to Health," and loose labels for labeling containers of celery, beet, and carrot juices.

LIBELED: 10–19–59, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the carrot juice was adequate and effective for the treatment or prevention of colitis, ulcers, lung hemorrhages, acne, anemia, rheumatic conditions, constipation, rickets, functional heart trouble, arthritis, boils and carbuncles, diabetes, cataracts, diphtheria, gonadal deficiency, Addison's disease, apoplexy, arteriosclerosis, cancers, and other diseases; that the celery juice was adequate and effective for the treatment or prevention of arthritis, rheumatism, gout, sciatica, neuralgia, neuritis, sore throat, chronic appendicitis, indigestion, hyper-acidity, cystitis, high blood pressure, dropsy, obesity, Addison's disease, anemia,

*See also Nos. 6364, 6368, 6370, 6372, 6373.

apoplexy, arteriosclerosis, measles, and other diseases, and was a good nerve tonic; and that the beet juice was adequate and effective for the treatment or prevention of varicose veins, arteriosclerosis, Addison's disease, low vitality, low blood pressure, suppressed menstruation, anemia, functional heart trouble, and other diseases, and that use of the article would regulate menstruation, dissolve calcium deposits, build blood, and act as a liver tonic.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: Health Champions, Inc., appeared as claimant and consented to the entry of a decree of condemnation and of permanent injunction. On 6–27–60, a decree was entered providing for the condemnation of the articles under seizure and the release under bond of the articles to be brought into compliance with the law. In addition, the decree permanently enjoined the claimant and its officers, agents, employees, representatives, and all other persons in active concert and participation with it from associating or causing to be associated with the above-described articles or any similar articles, while held for sale after shipment in interstate commerce, the booklets entitled "Raw Vegetable Juices" and "Natures Way to Health" or any written, printed, or graphic matter which represent and suggest that such articles are adequate and effective for the treatment or prevention of colitis, ulcers, lung hemorrhages, acne, anemia, rheumatic conditions, constipation, rickets, functional heart trouble, arthritis, boils and carbuncles, diabetes, cataracts, diphtheria, gonadal deficiency, Addison's disease, apoplexy, arteriosclerosis, measles, nerve disorders, varicose veins, low vitality, low blood pressure, suppressed menstruation, abnormal calcium deposits, and liver ailments.

6376. Electro-galvanic bracelets. (F.D.C. No. 44706. S. No. 36–202 P.)

QUANTITY: 60 devices at Lakewood, N.J.

SHIPPED: 10–1–58, from Trumbull, Conn., by Lev Sukacev.

LABEL IN PART: (Box) "Electro-Galvanic Bracelet New!"

ACCOMPANYING LABELING: Leaflet in box entitled "The Electro-Galvanic Bracelet."

RESULTS OF INVESTIGATION: Examination showed the article or device to be a white metal wrist bracelet. A clear plastic plate with imbedded loops of wire was attached under the "name plate," and a clear plastic piece was also attached under the "catch" links of the bracelet.

LIBELED: 7–11–60, Dist. N.J.

CHARGE: 502(a)—when shipped, the labeling of the device contained false and misleading representations that the article was an adequate and effective treatment for relieving body aches and pains, sciatica, arthritis, muscle inflammation, bursitis, neuritis, contusions, sprains, dislocations, and sinusitis; that the article might be contraindicated and should be used discriminately and with caution in such conditions as stomach ulcer, pulmonary tuberculosis, nerve injuries, malignancies, and in pregnancy, that the therapeutic value of the article had been established in experiments made by the Nanterre Hospital, France; and that the article was an "Electro Therapeutic Bracelet"; and 502(b)(1)—the label failed to bear the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 10–9–60. Default—1½ bracelets, which was the total number seized under the libel, were destroyed.

6377. Dr. Scholl's Foot Exercizer (sandals). (F.D.C. No. 44128. S. No. 28–605 R.)

QUANTITY: 52 ctns., each containing 1 pair of sandals of various sizes, at Minneapolis, Minn.

SHIPPED: 11–16–59, from Chicago, Ill., by Dr. Scholl's Foot Comfort Shops.

LABEL IN PART: (Ctn.) "Dr. Scholl's Foot Exercizer * * * The Scholl Mfg. Co., Inc."

ACCOMPANYING LABELING: Leaflet entitled "Dr. Scholl's Foot Exercizer" and folder entitled "Sensationally New! Dr. Scholl's Foot Exercizer Sandals."

LIBELED: 4–19–60, Dist. Minn.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for strengthening the entire structure of the foot; relieving and correcting arch sag and stiffened joints; reactivating and revitalizing weakened muscles in the feet and legs; increasing blood circulation to the feet and legs; returning feet to their normal strength, suppleness and elasticity, and overcoming callouses.

DISPOSITION: 9–15–60. Default—delivered to a charitable institution with the understanding that it be informed of the false and misleading labeling.

6378. Filtronair Air Purifier device. (F.D.C. No. 44510. S. No. 23–904 R.)

QUANTITY: 9 devices at Kansas City, Mo.

SHIPPED: 5–31–60 and 6–2–60 and on an unknown date, from Glendale, Calif., by Filtronair, Div. of Genge Industries, Inc.

LABEL IN PART: (Device) "Filtronair."

ACCOMPANYING LABELING: Booklets entitled "Is Dirty Air Choking Off Your Profits," "Is Breathing Killing You," and "Filtronair Electrostatic Precipitation."

RESULTS OF INVESTIGATION: The article consisted of a portable cabinet containing a honeycomb-shaped electrical precipitator, a mechanical filter, and a fan for continuous recirculating of room air through the filters.

LIBELED: 7–5–60, W. Dist. Mo.

CHARGE: 502(a)—when shipped, the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for relieving or overcoming colds, asthma, hay fever, bronchitis, virus conditions, flu, respiratory ailments, allergies, and many serious illnesses; provided complete protection against harmful air pollutants, and safeguarded health by removing irritants, bacteria, allergens, and viruses.

DISPOSITION: Genge Industries, Inc., claimant, having stipulated with the Government for the removal of the case to the Northern District of California, an order for such removal was entered on 8–12–60. On 9–23–60, Genge Industries, Inc., having consented to the entry of a decree, judgment of condemnation was entered by the United States District Court for the Northern District of California and the article was ordered released under bond for relabeling.

6379. Electronic Magnetic Instrument and Anapathic device. (F.D.C. No. 41299. S. Nos. 78–360/1 M.)

QUANTITY: 1 Electronic Magnet Model G device and 1 *Anapathic device* at Bethany, Okla.

SHIPPED: The Model G device was transported during 1955 or 1956, by Dr. C. W. Harper of Bethany, Okla., from L. L. Roby Mfg. Co., Tiffin, Ohio, and the *Anapathic device* was shipped in May 1950, from Kansas City, Mo., by Radiation Laboratories, Inc.

LABEL IN PART: "Electronic Magnetic Model G" and "Anapathic * * * Radiation Laboratories, Inc."

ACCOMPANYING LABELING: Leaflets entitled "Electronic Magnetic Instrument Model G * * * Prices F.O.B. Tiffin Ohio," "Electronic Magnetic Instrument Model G * * * Instructions"; and sets of instructions entitled "Anapathic Instructions."

RESULTS OF INVESTIGATION: The *Electronic Magnetic Instrument* contained components to provide an electronic circuit of low voltage, low frequency faradic current, and a magnetic circuit of low voltage electromagnetic energy of 220 cycles per second.

The *Anapathic device* was a wooden cabinet approximately 24" x 20" x 12" with an instrument control panel. The panel face contained two wells labeled "specimen" and "anapathic," an anapathic switch labeled "Neut 1" "Neut 2" "off" "scan" and "therapy," a power on-off switch, a start switch, power and scan lights and test switch number 0, 1, 2, 3, 4, two electrode pads approximately 4" x 5", with twin leads to plug into the panel which were labeled "collector" and "therapy." In the upper center of the front panel was a large timing dial. The back panel had prongs to which the power cord and ground leads were connected. There was also a 115v. AC convenience outlet.

LIBELED: 12–26–57, W. Dist. Okla.

CHARGE: 502(a)—when shipped, the labeling which accompanied the articles contained false and misleading representations that the Model G device was capable of treating body areas of congestion, inflammation and irritation; and of supplying stimulating energy to the body; and that the *Anapathic device* was capable of amplifying body energy; of implanting body energy in a media which could be used in the treatment of acute and chronic conditions; and of treating undulant fever, Streptococcus and meningococcus infections, carcinoma, tuberculosis, all colon disturbances, gas and all metallic poisons.

DISPOSITION: On 3–17–58, a default decree of condemnation was entered against the *Anapathic device* and it was delivered to the Food and Drug Administration.

C. W. Harper appeared and filed a claim for the Electromagnetic device.

Thereafter, the Government filed written interrogatories. Following the filing of answers to the interrogatories the Government filed a motion for summary judgment which was sustained on 5–27–60.

On 6–21–60, the Electromagnetic device was ordered condemned and delivered to the Food and Drug Administration.

DRUG FOR VETERINARY USE*

6380. Worm control preparation (veterinary). (F.D.C. No. 44302. S. No. 35–342 P.)

INFORMATION FILED: 5–13–60, M. Dist. Tenn., against John W. Griffith, t/a Blue Ace, Nashville, Tenn.

SHIPPED: 4–14–58, from Tennessee to Pennsylvania.

*See also No. 6362.

LABEL IN PART: (Btl.) "Blue Ace 1 Qt. Active Ingredients—Combined Iodine 3% Nicotine 18%—Inert Ingredients 79% Blue Ace Nashville, Tennessee Poultry–Turkey–Broiler (Large Round) Worm Control Preparation."

ACCOMPANYING LABELING: Circular entitled "Blue Ace from Incubator to Maturity."

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article would be adequate and effective in the treatment of worms in poultry; would provide larger, better quality eggs with harder shells; would contribute to greater egg production, more weight, and to lowered mortality rate in poultry; and that the use of the drug in controlling large roundworms would result in greater profits.

PLEA: Guilty.

DISPOSITION: 10–11–60. $100 fine and probation for 1 year.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6361 TO 6380

PRODUCTS

[1] (6367) Seizure contested.
[2] (6375) Injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6367) Seizure contested.
[2] (6375) Injunction issued.

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U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6381–6400

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default or by consent; (2) a criminal proceeding terminated upon a plea of nolo contendere; and (3) injunction proceedings terminated upon the entry of permanent injunctions by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *July 13, 1961.*

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*For presence of a habit-forming substance without warning statements, see No. 6383; omission of, or unsatisfactory, ingredients statements, Nos. 6384, 6385, 6396; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6384, 6385, 6396; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6384, 6385; cosmetic, actionable under the drug provisions of the Act, No. 6396.

597909—61——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6381–6400

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (National Formulary), and its quality and purity fell below the standard set forth in such compendium; and Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; Section 502(d), the article contained a chemical derivative of barbituric acid, and its label failed to bear the name and quantity or proportion of such derivative, and in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2) in the case where it was fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of alcohol; Section 502(f)(1), the labeling of the article failed to bear adequate directions for use and the article was not exempt from such requirement; Section 503(b)(1), the article was a drug intended for use by man which, because of its toxicity or other potentiality for harmful effect, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug and it was dispensed contrary to the provisions of such Section; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6381. Acutalyn. (F.D.C. No. 42492. S. Nos. 69–077 M, 83–679 M.)

INFORMATION FILED: 10–14–60, N. Dist. Calif., against Enzyme Products, Inc., San Leandro, Calif., and Wesley G. Irons, vice-president.

SHIPPED: On 6–12–57 and 6–21–57, from San Leandro, Calif., to Jackson Heights, N.Y., and Peoria, Ill.

LABEL IN PART: (Vial) "5 cc Single Dose Vial A C U T A L Y N For Intravenous Inject. Only ENZYME PRODUCTS, INC. San Leandro, Calif."

CHARGE: 505(a)—when shipped, the article was a new drug within the meaning of the law and an application filed pursuant to 505(b) was not effective with respect to such drug.

PLEA: Nolo contendere.

DISPOSITION: 12–12–60. Corporation—$500 fine; individual—$100 fine suspended.

6382. Trim-A-Drine timed disintegration capsules. (F.D.C. No. 43911. S. No. 77–702 P.)

QUANTITY: 100 capsules in bulk btls. and 34 retail btls. at Detroit, Mich., in possession of Marshall Drug Co.

SHIPPED: 8–10–59, from Philadelphia, Pa.

LABEL IN PART: (Bulk btl.) "Timcaps Phenylpropanolamine HCl. * * * 75 mg. * * * Each Timcap Contains: Phenylpropanolamine HCl_____75 mg. Medication released gradually over a period of approximately 8 to 10 hours. Effective orally for the symptomatic control of allergic manifestations, appetite depressant, and vasoconstrictor. Caution: * * * Dosage: * * * 10397 Lustgarten Laboratories, Inc., Philadelphia 31" and (retail btl.) "21 Timed-Caps * * * Trim-A-Drine True Appetite Depressant * * * Each Timed-Cap contains 75 mg. phenylpropanolamine HCl which is released over a period of 6–10 hrs. * * * Distributed by Marshall Drug Co., 14230 Curtis Ave., Detroit 35, Mich. 1039."

ACCOMPANYING LABELING: Flyers reading in part "True Appetite Depressant * * * Marshall Drug Co." and loose retail bottle labels.

LIBELED: 11–16–59, E. Dist. Mich.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that it was an appetite depressant and that it would cause one to become slim and lean; and 505(a)—the article was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 11–10–60. Consent—destruction.

6383. Delfeta-Sed Stedytabs and Delfeta-Sed plus T Stedytabs. (F.D.C. No. 44676. S. Nos. 3–801/2 R.)

QUANTITY: 2 drums, containing 42,000 tablets (Lot No. 996) and 61,000 tablets (Lot No. 997) respectively in bulk, 10,000 tablets in unlabeled cellophane bags, and 250 30-tablet pkgs. at Baltimore, Md.

SHIPPED: On 4–25–60 and 4–26–60, from St. Louis, Mo., by Victor M. Hermelin & Co.

LABEL IN PART: (Drum) "Lot No. 996 * * * Delfeta-Sed Stedytabs Each tablet contains: *Delfetamine 30 mg. #Sedafax 120 mg. (Warning: May be habit forming) * * * *Registered Trademark of dl-N-methyl-beta-phenylisopropylamine Hydrochloride. #Trademark of special micronized grade of Amobarbital, USP;" (drum) "Lot No. 997 * * * Delfeta-Sed plus T Stedytabs Each tablet contains: *Delfetamine 30 mg. #Sedafax 120 mg. (Warning: May be habit forming) §Triroid 2¼ gr. * * * *Registered Trademark of dl-N-methyl-beta-phenylisopropylamine Hydrochloride. #Trademark of special micronized grade of Amobarbital, USP §Trademark of triple-assayed Thyroid, USP;" and (30-tablet pkgs.) "Stedytabs Sustained Release Tablets Delfeta-Sed plus T Delfetamine with Sedafax & Triroid."

RESULTS OF INVESTIGATION: Investigation revealed that the 10,000 tablets in unlabeled cellophane bags were rejects of Lot No. 997; and that the 250 30-tablet packages contained tablets repacked by Eastern Research Laboratories, Inc., from Lot No. 997. The tablets of Lot No. 996 contained methamphetamine hydrochloride and amobarbital and those of Lot No. 997 contained methamphetamine hydrochloride, thyroid, and amobarbital.

LIBELED: 6–21–60, Dist. Md.

CHARGE: 502(d)—the articles contained a chemical derivative of barbituric acid, and their labels failed to bear the name of the drug and, in juxtaposition therewith, the statement "Warning: May be habit forming."; and 505(a)—the articles were new drugs which may not be introduced into interstate commerce, since applications filed pursuant to law were not effective with respect to such drugs.

DISPOSITION: 8–8–60. Default—destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

6384. Amphetamine sulfate (tablets and capsules). (F.D.C. No. 43626. S. No. 75–606 P.)

QUANTITY: Unknown quantity of tablets and capsules at Cairo, Ill.

SHIPPED: Prior to 10–26–59, from places outside the State of Illinois.

LIBELED: 10–28–59, E. Dist. Ill.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such labeling since the article was, or would, be in possession of persons not regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs and since the article was not to be dispensed as required by 503(b); 503(b)(1)—the article was a drug intended for use by man which, because of its toxicity or other potentiality for harmful effect and the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug and it was dispensed contrary to the provisions of such Section; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12–15–59. Default—delivered to the Food and Drug Administration.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

6385. Dextro-amphetamine sulfate tablets and capsules and amphetamine sulfate tablets and capsules. (F.D.C. No. 43553. S. No. 75–813 P.)

QUANTITY: Unknown quantity of tablets and capsules at Wyatt, Mo.

SHIPPED: On an unknown date from Cairo, Ill., by Thurman L. Wilkerson, also known as Bo Wilkerson.

LIBELED: 10–28–59, E. Dist. Mo.

CHARGE: 502(b)—when shipped, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and the article was not exempt from such labeling since the article was, or would be, in pos-

*See also No. 6384.

session of persons not regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs and since the article was not to be dispensed as required by 503(b); and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11–24–59. Default—delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6386. Amphetamine sulfate tablets. (F.D.C. No. 44199. S. Nos. 46–609/12 P.)

QUANTITY: 11 drums, each containing 50,000 tablets, 261 1,000-tablet btls., and 9 100-tablet btls., at Birmingham, Ala., in possession of Medical Specialties Corp.

SHIPPED: Between 7–21–58 and 11–25–59, from Houston, Tex., and Philadelphia, Pa.

LIBELED: 1–22–60, N. Dist. Ala.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since, although it was a prescription drug in possession of a wholesale distributor of prescription drugs, the exemption from bearing adequate directions for use had expired with respect to the article as provided in Regulation 1.106(b) because deliveries were, or would be, made contrary to 503(b).

DISPOSITION: 6–13–60. Default—destruction.

6387. Dainty-Maid Service. (Inj. No. 372.)

COMPLAINT FOR INJUNCTION FILED: 12–18–59, E. Dist. Mich., against Mrs. Wilma Becker, Detroit, Mich.

CHARGE: The complaint alleged that the defendant was engaged in selling and distributing an article designated by the name of "*Dainty-Maid Service*," consisting of a douche bag, a chrome-plated clamp, a box of "Dainty-Maid Personal Powder," a "Dainty-Maid Colonator," and a "Dainty-Maid 'Return-Flow' Earigator"; that the article was shipped to the defendant, from time to time, from Middlefield, Conn.; that while the article was being held for sale by the defendant after shipment in interstate commerce, the defendant, in the course of sales talks to prospective customers, caused oral representations to be made regarding the diseases, symptoms, and conditions for which the article was intended; and that defendant's act of making such oral representations resulted in the article being misbranded under 502(f)(1), in that the labeling failed to bear adequate directions for use in the treatment and prevention of the diseases, symptoms, and conditions for which the article was intended, namely, for preventing "female troubles," operations, including hysterectomies, cancer of the female parts, rot and decay in the vaginal tract, toxic poisons from entering the blood stream, and bladder trouble; for preventing and overcoming leukorrhea and painful or delayed menstruation; for overcoming Trichomonas infection and other conditions manifested by the presence of pus and inflammation, leukorrhea, sinus con-

*See also Nos. 6384, 6385.

ditions, hay fever and head colds; and for providing benefits to the bladder, kidneys, and related parts.

DISPOSITION: 12–18–59. The defendant having consented, the court entered a decree of permanent injunction enjoining and restraining the defendant from making or causing to be made any oral or written representations for the use of the article in the prevention or cure of any disease, condition, or infection of any kind which was not stated in the labeling of the article, while such article was held for sale after shipment in interstate commerce.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6388. Sulfapyridine sodium powder (2 seizure actions). (F.D.C. Nos. 44699, 44700. S. Nos. 41–268/70 R.)

QUANTITY: 1 100-lb. drum, 8 1-lb. btls., and 1 25-lb. drum, at San Francisco, Calif.

SHIPPED: The article was shipped in bulk, on 10–8–58, from New York, N.Y., by Fine Chemical Co.

LABEL IN PART: (Drum) "Sodium Sulfapyridine N.F.X. For Manufacturing Use Only Fine Chemical Company, New York, N.Y."; (btl.) "Sulfapyridine Sodium N.F. Powder (Not Sterile) Trico Pharmaceutical Co. Oregon City–San Francisco–Los Angeles"; and (drum) "Sulfapyridine Sodium N.F. Powder Not Sterile Trico Pharmaceutical Co."

RESULTS OF INVESTIGATION: A portion of the bulk drug was repacked into 8 1-lb. bottles and 1 25-lb. drum after shipment. Analysis showed that the drug contained less than 99 percent sulfapyridine sodium.

LIBELED: 7–5–60, N. Dist. Calif.

CHARGE: 501(b)—when shipped, the strength of the article differed from the standard set forth in the National Formulary.

DISPOSITION: 8–24–60. Default—destruction.

6389. Tweltone solution. (F.D.C. No. 44756. S. No. 22–273 R.)

QUANTITY: 48 cartoned vials at Kansas City, Mo.

SHIPPED: 4–4–60, from Indianapolis, Ind., by Pitman-Moore Co.

LABEL IN PART: "10 cc. size Sterile Solution Tweltone Liver Folic Acid B_{12} * * * Pitman-Moore Company Div. of Allied Labs., Inc., Indianapolis. Sterility Test: 19464 Serial Lot No. 22159070."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 50 percent of the declared amount of vitamin B_{12}.

LIBELED: On or about 7–26–60, W. Dist. Mo.

CHARGE: 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "Each cc. Represents: Vitamin B_{12} Activity * * * Equivalent to 10 Micrograms Cyanocobalamin, Fortified With Folic Acid, 10 mg. and Crystalline Vitamin B_{12} 50 Micrograms." was false and misleading.

DISPOSITION: 9–23–60. Default—destruction.

6390. Estrophen-B Regular Strength tablets. (F.D.C. No. 44732. S. No. 4–504 R.)

QUANTITY: 1 drum containing 18,000 tablets in bulk, 96 100-tablet btls., and 1 1,000-tablet btl., at Petersburg, Va.

SHIPPED: On 6–4–58, tablets were shipped in bulk drum, from Cleveland, Ohio.

LABEL IN PART: (Btl.) "Estrophen-B Regular Strength, Hexestrol, Phenobarbital and Vitamin B Complex Factors Each tablet contains: * * * Thiamine Hydrochloride 3 mg." and (drum) "Estrophen-B Regular Strength * * * Thiamine Hydrochloride 3 mg."

RESULTS OF INVESTIGATION: The tablets shipped in bulk were repacked in bottles by the dealer. Examination showed that the article contained approximately 70 percent of the declared amount of thiamine hydrochloride (vitamin B_1).

LIBELED: 7–19–60, E. Dist. Va.; amended 7–25–60.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported or was represented to possess; and 502(a)—while held for sale, the labeling of the article was false and misleading as applied to a product which contained less than the declared amount of thiamine hydrochloride.

DISPOSITION: 9–27–60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

6391. Lecithin. (F.D.C. No. 44438. S. Nos. 93–216 P, 93–218/20 P.)

QUANTITY: 37 8-oz. btls. and 28 1-lb. btls. of granular lecithin; 16 100-capsule btls. of No. 761 lecithin; 5 50-capsule btls., 13 100-capsule btls., and 4 250-capsule btls. of liquid lecithin; and 13 100-capsule btls. of soyalecithin and carotene, at Seattle, Wash.

SHIPPED: (Granular lecithin) 1–15–60, from Los Angeles, Calif., by William T. Thompson Co.; (No. 761 lecithin) 1–27–60, from New York, N.Y., by Approved Formulas, Inc.; (liquid lecithin) between 10–2–59 and 11–13–59, from Portland, Oreg., by Nu Vita Co.; and (soyalecithin and carotene) 10–20–59, from South Hackensack, N.J., by Schiff Bio Food Products, Inc.

LABEL IN PART: "Granular Form Wm. Luddy Co. Lecithin Derived From Soybeans * * * A Natural Vegetable phosphatide rich in unsaturated fatty acids * * * Wm. Luddy Company, Los Angeles 27, Calif. St. Louis 3, Mo."; "No. 761 Lecithin 8 Grains natural lecithin obtained from soybeans aids fat metabolism. * * * Manufactured for Approved Formulas, Inc., New York 36, N.Y."; "Soya Liquid Lecithin US Grade * * * Each capsule contains not less than 1200 mg. of N.S. grade Lecithin * * * Nu Vita Company, 1325 S.E. 9th Avenue Portland 14, Oregon"; and "Schiff Natural Lecithall Soyalecithin 370.6 mg. & Carotene Vitamin A 1000 units per capsule * * * Schiff Bio Food Products, Inc., So. Hackensack, N.J."

ACCOMPANYING LABELING: Photocopy of a newspaper article by Lelord Kordell entitled "Stay Alive Longer" appearing in the August 26, 1959 edition of a Seattle newspaper.

LIBELED: 4–19–60, W. Dist. Wash.

CHARGE: 502(a)—when shipped, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for the treatment and prevention of, atherosclerosis; pale and drawn face;

*See also Nos. 6382, 6389, 6390.

nervousness; weak, jangly nervous system; insomnia; irritability; nervous, mental, and glandular overactivity; exhaustion; loss of vitality of the cerebrospinal fluid; nerve and gland exhaustion; nervous breakdown; headaches; brain fag; senility; nervousness; tension; shattered nerves; depleted brain power; waning activity of vital glands; depletion of fatty myelin sheath of nerves; sexual decline; and fat infiltration of the liver and other organs; and that the articles would effect a strong nervous system; improve the functioning of the brain, nervous system, endocrine glands, muscles of the heart and kidneys; neutralize body poisons of internal and external origin; prevent fat settling on artery walls; and restore life forces; and that the granular lecithin was adequate and effective to lower the cholesterol level of the blood.

The libel alleged also that the articles were misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods, No. 26797.

DISPOSITION: 6–17–60. Default—destruction.

6392. Gelatin Plus capsules. (F.D.C. No. 44688. S. Nos. 25–917/8 R.)

QUANTITY: 106 ctns., each containing 12 boxes of 90 capsules each; 96 ctns., each containing 12 boxes of 30 capsules each; 285 ctns., each containing 8 boxes of 30 capsules each; 156 ctns., each containing 1 box of 30 capsules each; 2 boxes of 5 capsules each; and 1 box of 15 capsules, at Santa Monica, Calif., in possession of Gelatin Plus, Inc.

SHIPPED: On 4–8–60 and 5–17–60, quantities of bulk gelatin were shipped from Detroit, Mich.

LABEL IN PART: (Box) "Gelatin-Plus for Problem Nails * * * Ten-Gr. Capsules * * * A pure High Protein Sugarless Gelatin containing natural Amino Acids with added Assimilable Calcium in the ratio of the proportion of the Adult Daily Requirement .009% Directions * * * Distributed by Gelatin Plus * * * Santa Monica, Calif."

RESULTS OF INVESTIGATION: The bulk gelatin, after its shipment as described above, was encapsulated and packaged by Gelatin Plus, Inc.

LIBELED: 6–27–60, S. Dist. Calif.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was effective for the treatment of problem nails that split, chip, peel, and break, and that it would produce "nail beauty."

DISPOSITION: 10–30–60. Default—destruction.

6393. Concentrated extract of alfalfa. (F.D.C. No. 44666. S. No. 41–445 R.)

QUANTITY: 8 cases, 24 8-oz. btls. each; 6 cases, 13 16-oz. btls. each; and 9 cases, 12 32-oz. btls. each, at San Francisco, Calif.

SHIPPED: 6–8–59 and 1–8–60, from American Fork, Utah, by Lucerne Laboratories of Utah.

LABEL IN PART: (Btl.) "Lucerne Concentrated extract of alfalfa (Medicago Sativa) it is a dietary supplement * * * Lucerne Is Not A Medicine One teaspoonful (5 Mls) contains: * * * 0.00586 Mg. Iron Three glasses daily furnish: * * * 0.02 mg. 12% of Min. Daily Reqt. * * * Also micro-amounts of the many other elements present, (and combined naturally) in the Lucerne,—the oldest known plant—from which made; for which elements no official standard of requirement has been established. Many of these elements may be deficient in foods of every day variety. * * * All materials used in the

manufacture of Lucerne are of USP XIII, National Formulary VIII, or of CP (Reagent) quality and are so guaranteed * * * Lucerne Laboratories of Utah * * * American Fork, Utah."

ACCOMPANYING LABELING: Leaflet entitled "Lucerne * * * Alfalfa Nature's Rarest Gift to Man and Animal."

LIBELED: 6–17–60, N. Dist. Calif.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for, and preventive of, tiredness and asthma; and that the article would soothe the nervous system; produce health, promote every secretion of the body; regulate acidity; expel waste matter; keep joints and tendons supple; promote proper alkaline-acid balance in body fluids; dissolve uric acid so it would pass through the kidneys; promote the growth of skin, hair, and nails, and maintain a good lens of the eye and clear vision; keep body membranes healthy; increase digestive ability; stabilize nerves; promote growth and healing; sweeten the breath; increase peristaltic action of the bowels; stimulate the appetite; and preserve the teeth.

The libel alleged also that the article was misbranded under the provisions of the law relating to foods as reported in notices of judgment on foods.

DISPOSITION: 8–29–60. Consent—claimed by Lucerne Laboratories of Utah, and released for relabeling.

6394. Kelp-Ette tablets. (F.D.C. No. 43959. S. No. 79–796 P.)

QUANTITY: 24 500-tablet btls., 24 1,000-tablet btls., and 24 2,000-tablet btls., at Hobart, Ind., in possession of Nelson's Natural Foods.

SHIPPED: Powdered kelp was shipped on 11–19–57, from Outer Harbor, San Pedro, Calif.

LABEL IN PART: (Btl.) "5-Grain Tablets * * * Nelson's Kelp-Ettes * * * A Pure Vegetable Sea Food Containing an abundance of Safe Natural Iodine Plus Other Minerals, Trace Elements, Organic Compounds and Vitamins Pressed from Pure Ocean Kelp. * * * Packed and Distributed by Nelson's Natural Foods * * * Battle Creek, Michigan * * * Nelson's Kelp-Ettes also contain Traces of the following Vitamins: Choline-Niacin-Carotene-Riboflavin Plus the following Organic Compounds: Alginic Acid-Chlorophyll-Lecithin-Manitol * * * 18 tablets * * * contain in milligrams * * * iron 5.8 * * * also undeterminable small amounts of Trace Elements of: Aluminum, Barium, Boron, Chromium, Lithium, Nickel, Silicon, Silver, Strontium, Titanium, Vanadium and Zinc."

ACCOMPANYING LABELING: Leaflets entitled "More Buoyant Health" and loose bottle labels for all size bottles.

RESULTS OF INVESTIGATION: The *Kelp-Ette tablets* were manufactured by the dealer from powdered kelp which had been shipped as described above. Examination showed that the tablets contained approximately 50 percent of the declared amount of iron.

LIBELED: 12–14–59, N. Dist. Ind.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for developing more pep; better and more buoyant health; and a fuller, richer life.

The libel alleged also that the article was adulterated and misbranded under the provisions of the law relating to foods as reported in notices of judgment on foods.

DISPOSITION: 8–10–60. Default—destruction.

6395. Vitamin tablets. (F.D.C. No. 44751. S. Nos. 7–188/93 R.)

QUANTITY: 3 5,000-tablet cartoned btls., 32 1,000-tablet cartoned btls., 3 cases, each containing 48 250-tablet btls., 8 cases, each containing 144 100-tablet cartoned btls., and 3 cases, each containing 144 50-tablet cartoned btls., of *Vita-Kaps;* 7 1,000-tablet cartoned btls., 45 cases, each containing 12 250-tablet cartoned btls., 6 cases, each containing 12 100-tablet btls., and 14 cases, each containing 12 50-tablet cartoned btls., of *VitaKaps-M;* 6 5,000-table btls., 6 1,000-tablet btls., 7 cases, each containing 48 250-tablet btls., 342 cases, each containing 12 100-tablet btls., and 4 cases, each containing 144 50-tablet btls., of *Dayalets;* 3 1,000-tablet btls., 13 cases, each containing 36 250-tablet btls., and 136 cases, each containing 12 100-tablet btls., of *Dayalets-M;* 3 cases, each containing 24 1,000-tablet cartoned btls., 85 cases, each containing 48 100-tablet btls., and 16 cases, each containing 48 30-tablet btls., of *Optilets;* and 4 1,000-tablet btls., 20 cases, each containing 48 100-tablet btls., and 12 cases, each containing 48 30-tablet btls., of *Optilets-M*, at Needham Heights, Mass.

SHIPPED: Between 3–5–60 and 5–4–60, from North Chicago, Ill., by Abbott Laboratories.

LABEL IN PART: (Btl.) "Vita-Kaps Abbott Multivitamins for all the family A, D, C, and Vitamin B Complex, including B_{12} ("VitaKaps-M Abbott Multivitamins and Minerals for all the family. A, D, C and Vitamin B Complex, including B_{12} and Minerals," "Dayalets Abbott's Multiple Vitamin Tablets Potent, daily maintenance vitamins 10 important vitamins in each tiny tablet," "Dayalets-M Abbott Vitamin Mineral Tablets 10 Important Vitamins 9 Important Minerals," "Optilets * * * Therapeutic Formula Multivitamins," and "Optilets-M Abbott's Therapeutic Formula Vitamins with Minerals") * * * Abbott Laboratories, North Chicago, Illinois."

ACCOMPANYING LABELING: Leaflets entitled "Vitamins for Your Family."

LIBELED: 8–3–60, Dist. Mass.

CHARGE: 502(a)—the labeling accompanying the articles, when shipped, contained statements which represented and suggested that additional quantities of vitamins, far in excess of the amount recommended for adequate nutrition, would provide additional benefits to persons in good health; and would assist in returning a sick or injured person, or one convalescing from an operation, to good health; that the body has a greatly increased need for vitamins when the individual is under mental stress, tension, or strain, is physically fatigued, or is suffering from injury, infection, or illness, or is undergoing surgery, and which increased need is an indication for the use of the excess quantities of vitamins offered by the products, which statements were false and misleading, since they were contrary to fact;

502(a)—the labeling accompanying the articles, when shipped, contained statements which represented and suggested that the products were offered as a medicine and as a preventive medicine for the treatment and prevention of night blindness; beriberi; pellagra; scurvy; rickets; osteomalacia; and nutritional macrocytic anemia; and suggested that these diseases are quite likely to occur unless the ordinary diet of the usual person in this country is supplemented by a vitamin or vitamin and mineral supplement, which statements were false and misleading, since the occurrence of such

diseases is extremely rare in this country and could occur only with the use of an extremely limited diet over a long period of time;

502(a)—the labeling accompanying the articles, when shipped, contained statements which represented and suggested that pernicious anemia results from a dietary deficiency of vitamin B_{12}, and would be corrected by supplementation of the diet with that vitamin, which statements were false and misleading, since lack of intrinsic factor is a result of failure of the function of the body to produce that factor, leading to the disease, pernicious anemia, which disease is not amenable to treatment or correction, nor can the intrinsic factor be replaced by use of the supplements offered; and

502(a)—the listing, in the accompanying labeling of the articles, of the following symptoms: defects of tooth development; swollen bleeding gums; gingivitis; lip and skin lesions; skin and tongue inflammation; skin hemorrhages; seborrheic dermatitis; optical disturbances; gastrointestinal disturbances; vomiting of pregnancy; nerve diseases; dysfunction of the nervous system; convulsions; impaired growth; and muscular weakness as the result of a deficiency of one or more of the vitamins contained in the products; suggested that anyone suffering from one or more of these conditions and symptoms was suffering from a dietary deficiency and could eliminate the symptoms and conditions by adding a vitamin supplement to their diet, which suggestion was false and misleading, since it is contrary to fact in that such conditions and symptoms are rarely due to a dietary deficiency, are more commonly due to other causes not related to a dietary deficiency, and are not amenable to treatment with a vitamin supplement.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 9–19–60. Default—delivered to a charitable institution.

6396. Palm Beach Skin Specialists Lotion. (F.D.C. No. 44715. S. No. 28–831 R.)

QUANTITY: 23 4-oz. btls., 40 8-oz. btls., and 6 16-oz. btls., at Fargo, N. Dak.

SHIPPED: Between 2–18–60 and 7–13–60, from Minneapolis, Minn., by Miriam Collins Palm Beach Cosmetic Co.

LABEL IN PART: (Btl.) "Palm Beach Skin Specialists Lotion * * * Contains hexachlorophene, resorcinal, allantoin, and ethanol."

ACCOMPANYING LABELING: Booklet attached to each bottle entitled "Beautiful Skin is Clean Skin Palm Beach Skin Specialists Lotion."

LIBELED: 7–13–60, Dist. N. Dak.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for pimples, blackheads, enlarged pores, itching, eczema, sunburn, dandruff, for building tissue, impetigo, burns, scalds, wounds, and other skin conditions; and that it was a new hope for acne sufferers; 502(b)(2)—the bottle label failed to bear an accurate statement of the quantity of the contents; and 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient and the quantity, kind, and proportion of alcohol contained therein.

DISPOSITION: 7–29–60. Default—destruction.

6397. Plasmatic therapy device. (Inj. No. 359.)

COMPLAINT FOR INJUNCTION FILED: 9–11–59, S. Dist. Ind., against Physical Medicine Instrument Co., a corporation, Indianapolis, Ind., and Eulalia Op-

perman, president, A. Henry Opperman, secretary-treasurer, and Homer A. Keller, vice president.

ACCOMPANYING LABELING: Booklets headed "Warning" and "The Blood is the Life"; book entitled "Practical Physical Therapy"; and loose-leaf book formerly entitled "Twenty Years Record"; circular headed "Re: Plasmatic Therapy"; and sheet headed "Technical Information."

RESULTS OF INVESTIGATION: Examination showed that the device was a metal cabinet with a control panel containing lead-in wires for an alternating current electric power line and for any of the various applicators, a timer dial, a double-throw switch, a Variac voltage transformer, and various electrical connections; that it was essentially an indicator and timing device for the applicators; that the accessories included: two systemic applicators, one infrared applicator, one vaginal applicator, one rectal applicator, a jiffy wrapper, pillow and plastic sheet, stockinet covers for pads, a metal stand on casters, and line cords; and that the applicators were long, plastic sheets wound with resistance wires. The device also included "Eye Goggles" consisting of a plastic case equipped with michrome resistance wire fixed on asbestos and an "Eye Control Unit" (which is essentially a timer) consisting of a small metal cabinet with an input plug, a switch, a rheostat, a timer, and an output plug.

CHARGE: The complaint alleged that the defendants were engaged in the business of promoting, selling, servicing, replacing, and repairing a device called the "*Plasmatic therapy device*" which included an "Eye Control Unit" and "Goggles," as well as attachments, parts, accessories, and labeling thereof; that the device had been and was being sold to chiropractors, naturopaths, physiotherapists, masseurs, and other nonmedical practitioners; that the business of the defendants was then largely confined to servicing and supplying parts for the devices in the possession of such users; that the device furnished nothing more than a mild form of heat; that the device had no therapeutic effect; and that when shipped, the device was misbranded as follows:

502(a)—the labeling accompanying the article contained statements which represented and suggested that the device had therapeutic usefulness in the treatment and cure of arthritis, syphilis, septicemia, uremia, pneumonia, hemiplegia, diabetes, Bright's disease, cirrhosis of the liver, dementia praecox, chronic cardiac conditions, chronic infections, dropsy, encephalitis, epilepsy, Parkinson's disease, hypertension, hypochondria, locomotor ataxia, mental disorders, metabolic disorders, multiple sclerosis, neuralgia, malarial fever, jungle rot, poliomyelitis, neuritis, sciatica, neurasthenia, pleurisy, psoriasis, glaucoma, conjunctivitis, stye, corneal ulcer, scleritis, toxemic iritis, optic atrophy, acute middle ear catarrh, tinnitus, hemorrhoids, pruritus ani, and leukorrhea, which statements were false and misleading since the device had no therapeutic usefulness in the treatment and cure of the diseases and conditions stated and implied; or for any other diseases or conditions since the device possessed no therapeutic usefulness whatsoever.

The complaint alleged further that the defendants continued to advertise the devices and were preparing additional labeling; that the stock of parts on hand, sufficient to repair many hundreds of devices, constituted a menace to interstate commerce; and that such repair and replacement service allowed many operators of the devices to continue to use them in the treatment of serious diseases for which the devices were recommended but for which they were useless.

DISPOSITION: 9–26–60. The defendants having consented without either admitting or denying the allegations of the complaint, the court entered a decree of permanent injunction enjoining the defendants from—

(a) introducing or delivering for introduction or causing to be introduced or delivered for introduction into interstate commerce, any device designated as "*Plasmatic therapy device*" including its components, parts, and accessories or the same device by any other designation, or any similar device, which is accompanied by the booklets headed "Warning" and "The Blood is The Life"; the book entitled "Practical Physical Therapy"; the loose-leaf book formerly entitled "Twenty Years Records"; the circular headed "Re: Plasmatic Therapy"; or the sheet headed "Technical Information," or by any other written, printed, or graphic matter which represents and suggests that the device has therapeutic usefulness in the treatment and cure of the diseases and conditions named in the complaint;

(b) doing or causing to be done any act with respect to any device designated as "*Plasmatic therapy device*" including its components, parts, and accessories, or the same device by any other designation, or any similar device, while such device is held for sale after shipment in interstate commerce, which will result in such device being accompanied by the aforesaid labeling, or by other written, printed, or graphic matter containing the same representations and suggestions;

(c) introducing or delivering for introduction or causing to be introduced or to be delivered for introduction into interstate commerce, any device designated as "*Plasmatic therapy device*" including its components, parts, and accessories, or the same device by any other designation, or any similar device, which fails to bear in its labeling all of the conditions, purposes, and uses for which such device is intended and for which it is represented, by any means, to the public.

6398. Radiant Cosmic Disc and Radiant Spark-O-Life. (F.D.C. No. 45021. S. Nos. 41–284/6 R.)

QUANTITY: 9 discs (1-gal. size), and 2 discs (5-gal. size), known as *Radiant Cosmic Discs;* and 16 discs (1-gal. size) known as *Radiant Spark-O-Life*, at Oakland, Calif. Each disc was packaged in an envelope.

SHIPPED: On or about 5–13–60, from Tumtum, Wash., by Thomas Health Enterprises.

LABEL IN PART: (Envelope) "Radiant * * * Cosmic Disc Radiant Laboratories Leads the Nation in Natural Organic Food Growing Supplies Tum Tum, Washington;" and "Radiant * * * Spark-O-Life For Fowl and Animals Radiant Laboratories Leads the Nation in Natural Organic Food Growing Supplies Tum Tum, Washington."

ACCOMPANYING LABELING: Mimeographed booklets entitled "Announcing Radiant Living" and "Index for Radiant Analysis Kits"; and one-page sheets entitled "Join Radiant Associates, Inc."

RESULTS OF INVESTIGATION: Examination showed that the articles were gray-colored, solid, porous, disc-shaped devices of various sizes, as follows: (1-gal. size) $1\frac{15}{16}$'' in diameter x $\frac{3}{4}$'' thick; (1-gal. size) $2\frac{5}{16}$'' in diameter x $1\frac{1}{2}$'' thick; and (5-gal. size) $2\frac{11}{16}$'' in diameter x $1\frac{1}{2}$'' thick.

In use, the discs were allowed to soak, usually for 24 hour periods, in one- or five-gallon containers of water (depending on the size of the discs). The disc reportedly served to treat the water with natural cosmic rays. The

treated water purported to have all of the beneficial effect attributed to it in the labeling of the articles.

LIBELED: 10–14–60, N. Dist. Calif.

CHARGE: 502(a)—the labeling accompanying the articles, when shipped, contained false and misleading representations that the articles were an adequate and effective treatment for detecting the presence of toxins and the absence of needed elements in the body; restoring and maintaining health, increasing growth in poultry, restoring virility and vitality to livestock and poultry, eliminating sterility and sickness in livestock and poultry, destroying putrefactive and pathogenic bacteria, improving flavor and quality of foods, neutralizing atomic radiation and poison spray contamination in foods, making contaminated food and water safe for consumption, eliminating cancer, ulcers, tuberculosis, Bang's disease, corrhiza, and other sicknesses in poultry and cattle, increasing vitamin, protein, and other nutritional values in foods, and that the consumption of foods grown on radiant disc-treated soils would prevent disease conditions and bring about recovery from disease in man and other animals.

DISPOSITION: 11–17–60. Default—delivered to the Food and Drug Administration.

6399. Neurolectronic device. (F.D.C. No. 44709. S. No. 91–512 P.)

QUANTITY: 1 device at Denver, Colo.

SHIPPED: In February 1958, from Glendale, Calif., by W. B. Pearson.

LABEL IN PART: "Neurolectronics, Glendale, California, Patent Pending."

ACCOMPANYING LABELING: Pamphlet entitled "To the Doctor" and a leaflet entitled "Treatment Suggestions."

RESULTS OF INVESTIGATION: Investigation showed the device to be an electrically operated device, producing pulsed alternating current to four pads soaked in saline solution and applied to the body during treatment. The device included various intra-cavitary electrodes.

LIBELED: 7–11–60, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was an adequate and effective treatment for relieving or overcoming headaches; bursitis; spondylitis, arthritis; neuritis; sciatica; peripheral vascular disease; duodenal ulcer; indolent ulcer; rheumatic disorders; inflammatory conditions; sprains; fractures; neuromas; prostatitis; cystitis; hemorrhoids; constipation; high blood pressure; and numerous other diseases and abnormal conditions.

DISPOSITION: 9–6–60. Default—delivered to Food and Drug Administration.

DRUG FOR VETERINARY USE

6400. Worm-Kill. (F.D.C. No. 44710. S. No. 19–185 R.)

QUANTITY: 9 5-lb. bags at Tucumcari, N. Mex.

SHIPPED: 5–16–58, from Durango, Colo., by Colorado Livestock Chemical Co.

LABEL IN PART: (Bag) "Worm-Kill 'The All-Purpose Wormer' * * * Contents: Nicotine, Sulfur, Potash, Copperas, Phenothiazine."

LIBELED: 7–5–60, Dist. N. Mex.

CHARGE: 502(a)—when shipped, the labeling contained false and misleading representations that the article was effective for treating all types of worm

infestation in livestock and poultry and preventing infestations by ticks and lice in livestock and poultry.

DISPOSITION: 8–10–60. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6381 TO 6400

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6387, 6397) Injunction issued.

[1] (6387, 6397) Injunction issued.

U.S. GOVERNMENT PRINTING OFFICE: 1961

Missing: 6401-6420

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6421-6440

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce, or while held for sale after shipment in interstate commerce. These cases involve seizure proceedings in which decrees of condemnation were entered after default, consent, or motion for summary judgment. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *August 25, 1961.*

CONTENTS*

*For presence of a habit-forming substance without warning statements, see No. 6422; omission of, or unsatisfactory, ingredients statements, Nos. 6423, 6426; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 6423, 6438; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6423, 6436; cosmetics, actionable under the drug provisions of the Act, Nos. 6426, 6438.

602814—61

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6421–6440

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; Section 502(e), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear (1) the common or usual name of the drug, and (2), in the case where the article was fabricated from two or more ingredients, the common or usual name of each active ingredient; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

New-drug violation, Section 505(a), the article was a new drug within the meaning of Section 201(p), which was introduced into interstate commerce, and an application filed pursuant to Section 505(b) was not effective with respect to such drug.

NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

6421. Complex Z.A. (F.D.C. No. 44848. S. No. 32–875 R.)

QUANTITY: 29 ctns., 10 ampuls each, at New York, N.Y.

SHIPPED: During April 1960, from London, England, by Multipax Chemicals, Ltd.

LABEL IN PART: (Ctn.) "10 x 2.2 ml. Ampoules Complex Z.A. Each ampoule contains 2.2 ml. sterile aqueous solution of Zinc-Magnesium-Ascorbic Acid complexes equivalent to: Zinc Oxid. B.P. 1.85 mg. Mag. Chlorid. B.P.C. 3.00 mg. Acid. Ascorbic B.P. 30.00 mg. in 1 ml. Batch No. 108 * * * Edenhall Pharmaceutical Laboratories, Ltd. Sole Distributors: Multipax Chemicals Limited 142–146, Larkhall Lane, London, S.W. 4."

ACCOMPANYING LABELING: Leaflet in each carton entitled "To The Medical Profession Only * * * a new form of treatment in inoperable Neoplasm" and booklets entitled "To the Medical Profession Only Introducing 'Complex Z.A.' as a New Treatment for Inoperable Malignancy . . ."

LIBELED: 8–18–60, S. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for inoperable neoplasm, advanced malignancy, leukemia, Hodgkin's disease, and inoperable cancer; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: 9–16–60. Default—destruction.

6422. Phyltone capsules. (F.D.C. No. 42811. S. Nos. 24–177/9 P.)

QUANTITY: 57 100-capsule btls. and 33 30-capsule btls. at Phoenix, Ariz.

SHIPPED: Between 11–29–58 and 1–21–59, from Boling, Tex., by Texophyl Corp.

LABEL IN PART: (Btl.) "Phyltone Capsules Each Capsule Contains: ¼ Gram or 3¾ Grains Potassium Hydrogen Phytochlorin. Indicated for the treatment of Arteriosclerosis Arthritis and conditions of similar etiology. Manufactured by Texophyl Products, Boling, Texas. Dosage One capsule daily" and "Phyltone * * * ½ Gram Plant Porphyrins Dosage One Per Day Texophyl Corp. Boling, Texas."

ACCOMPANYING LABELING: Brochure entitled "Phyltone A Porphyrin Compound."

LIBELED: 2–9–59, Dist. Ariz.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for (on bottle label) arteriosclerosis, arthritis, and conditions of similar etiology, and (in brochure) resistant anemia, muscular atrophy, osteoporosis, impaired cerebration, depressive states, exhaustion, fatigue and manifest anoxia; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

DISPOSITION: 2–1–61. Texophyl Corp., claimant, having answered the interrogatories filed by the Government and failing to pursue the matter further, and being in default, judgment of condemnation was entered and the article was ordered destroyed.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6423. Amphetamine tablets or capsules. (F.D.C. No. 44358. S. Nos. 70–946 P, 70–948 P, 70–952 P.)

QUANTITY: 15,000 *amphetamine tablets*, and an unknown quantity of *amphetamine tablets or capsules*, in possession of Chester Menk, t/a Shifting Sands Truck Stop, and Elmer Menk, in the vicinity of Oaktown, Ind.

SHIPPED: Prior to 3–2–60, from outside the State of Indiana.

LIBELED: On or about 3–2–60, S. Dist. Ind.

CHARGE: 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the label of the article failed to bear the common or usual name of the drug; 502(f)(1)—the labeling of the article failed to bear adequate directions for use, and the article was not exempt from such requirement since the article was in the possession of persons who were not regularly and law-

fully engaged in the manufacture, transportation, storage, or distribution of prescription drugs, and since the article was not to be dispensed upon prescription, as required by 503(b)(1); and 503(b)(4)—the article was a drug subject to the provisions of 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7–15–60. Default—delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6424. Amphetamine tablets or capsules and barbiturate tablets or capsules. (F.D.C. No. 45098. S. Nos. 3–758/9 R.)

QUANTITY: 135,000 amphetamine tablets or capsules and 10,000 barbiturate tablets or capsules at Baltimore, Md., in possession of Edward Michael Horvath.

SHIPPED: 11–20–60, from outside the State of Maryland.

LIBELED: 11–21–60, Dist. Md.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use and the articles were not exempt from that requirement since they were prescription drugs in the possession of a person not lawfully engaged in distributing or dispensing prescription drugs.

DISPOSITION: 12–13–60. Default—delivered to the Food and Drug Administration.

6425. W & S Protein 90. (F.D.C. No. 44854. S. No. 20–470 R.)

QUANTITY: 9 cases, each containing 6 pkgs., each pkg. containing 1 30-capsule btl. and 1 360-tablet btl., at Warren, Mich.

SHIPPED: 4–13–60, from Riverside, Calif., by Ward & Stalnaker.

LABEL IN PART: (Pkg.) "W & S Protein 90 * * * Package contains 360 tablets W & S Protein 90 30 capsules W & S Protein 90 Supplement * * * Each tablet contains: Protein (Natural Meat) 90% Moisture 3% Ash 7% Carbohydrates 0 Fat 0 Supplement Ingredients: Sodium Carboxy Methyl Cellulose 8 grains Phenylasitin (conc. Prune) 9.5 mg. Essential Amino Acids; Natural Amino Acids of meat proteins essential in the daily diet * * * W–S Sales Riverside, California."

ACCOMPANYING LABELING: Folders entitled "Secrets of Natural Health" and "Secrets of Weight Control."

RESULTS OF INVESTIGATION: Analysis of the article showed that it contained approximately 75 percent of the declared amount of protein.

LIBELED: 8–29–60, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective for reducing and for the control of body weight, and thus to prevent heart failure, heart disease, varicose veins, gall-bladder trouble, arthritis, ruptures, hernia, cancer, diabetes, hardening of the arteries, high blood pressure, osteoarthritis of the lower back and knees, flat feet and other orthopedic disorders, psychoneurosis, and other serious diseases; and that the article would produce longevity; energy; strength, radiant health, maintain normal body weight,

*See also No. 6423.

produce a healthful, vigorous, youthful life, pep, vim, vigor, vitality, better appearance, happiness, rich blood, and step up the metabolism of the body; and 502(f)(2)—the article contained an irritant laxative and its labeling failed to warn that it should not be used when symptoms of appendicitis are present and that its frequent or continued use might result in dependence on laxatives.

The article was alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 10–7–60. Default—destruction.

6426. Cannolene tetter salve and Cannolene scalp ointment. (F.D.C. No. 44886. S. Nos. 4–659/60 R.)

QUANTITY: 130 1-oz. jars and 14 2½-oz. jars of salve and 18 3-oz. cans of ointment at Baltimore, Md.

SHIPPED: Sometime in January or February 1960, and 7–5–60, from Atlanta, Ga., by Cannolene Co.

LABEL IN PART: (Jar) "Cannolene Tetter Salve" and (can) "Cannolene Scalp Ointment."

ACCOMPANYING LABELING: Leaflets entitled "You Can Get Relief From."

RESULTS OF INVESTIGATION: An establishment inspection showed that the tetter salve contained petrolatum, sulfur, ammoniated mercury, and oil of tar and that the scalp ointment contained petrolatum, pine tar, and oil of cade.

LIBELED: 9–8–60, Dist. Md.

CHARGE: 502(a)—when shipped, the labeling of the salve contained false and misleading representations that the article was an adequate and effective treatment for growing hair, dandruff, itching scalp and other scalp disorders, scalp conditioning, and tetter; and the labeling of the ointment contained false and misleading representations that the article was effective in the treatment of splitting, breaking, and falling hair; 502(e)(2)—the tetter salve was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient, since sulfur and oil of tar were not declared on the label; and 502(f)(2)—the labeling of the tetter salve failed to warn that use of the article should be discontinued if rash or irritation developed, or if the condition persisted for which it was used; and that frequent or prolonged use, or application to large areas of the body may cause serious mercury poisoning.

DISPOSITION: 10–12–60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

6427. Secobarbital sodium capsules. (F.D.C. No. 44754. S. No. 31–173 R.)

QUANTITY: 24 500-capsule btls. at Houston, Tex.

SHIPPED: 5–19–60, from Chicago, Ill., by Kasar Co.

LABEL IN PART: "1918 500 capsules Secobarbital Sodium, 1½ Grain—2153."

RESULTS OF INVESTIGATION: Examination showed that the article failed to comply with the United States Pharmacopeia specification for uniformity of drug content per individual capsule.

LIBELED: On or about 7–22–60, S. Dist. Tex.

CHARGE: 501(b)—when shipped, the article purported to be a drug, *secobarbital sodium capsules*, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in such compendium.

DISPOSITION: 10–7–60. Default—destruction.

6428. Higadoce Forte injection. (F.D.C. No. 44734. S. No. 6–360 R.)

QUANTITY: 8 10-cc. vials at Wakefield, R.I.

SHIPPED: 3–9–60, from Worcester, Mass.

LABEL IN PART: (Vial) "HIGADOCE Forte 10 cc. Each cc. contains: Vitamins B_{12} Crystalline 60 mcg. Liver injection Crude (2 U.S.P. Units per cc.) For intramuscular use."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 76 percent of the declared amount of vitamin B_{12}.

LIBELED: 7–22–60, Dist. R.I.

CHARGE: 501(c)—while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statement "Vitamins B_{12} Crystalline 60 mcg." was false and misleading.

DISPOSITION: 8–16–60. Default—destruction.

6429. Rubber prophylactics. (F.D.C. No. 44865. S. Nos. 45–469/70 R.)

QUANTITY: 253 gross, in bulk in polyethylene bags, within cardboard boxes, and 900 gross, packed in 36 25-gross ctns., each containing 72 2-unit pkgs., at Durham, N.C., in possession of Barnett Coin Machine & Distributing Co.

SHIPPED: 6–30–60, from Akron, Ohio.

LABEL IN PART: (Box) "T–S–R 50 Gr. OP UN 2–24–6 O–N–E L/26" and (2-unit pkg.) "Safe-Tex * * * Prophylactics."

RESULTS OF INVESTIGATION: Investigation revealed that the dealer had repacked and relabeled the 2-unit packages from the bulk lot described above. Examination of both lots showed that 1.1 percent of the units examined were defective in that they contained holes.

LIBELED: 8–22–60, M. Dist. N.C.

CHARGE: 501(c)—while held for sale, the quality of the article fell below that which it purported to possess; 502(a)—the label statement "Sold and Intended to be Used as a Preventive of Disease" was false and misleading as applied to a product which contained holes.

DISPOSITION: 9–23–60. Default—destruction.

6430. Rubber prophylactics. (F.D.C. No. 44849. S. No. 2–964 R.)

QUANTITY: 250 ctns., each containing 48 3-unit plastic vials, at Durham, N.C., in possession of Barnett Coin Machine & Distributing Co.

SHIPPED: 1–16–60, from Akron, Ohio.

LABEL IN PART: (Vial) "Triple 'A' Brand Nipple End Prophylactics."

RESULTS OF INVESTIGATION: The article was repacked into vials from bulk lots and labeled as described, by the Barnett Coin Machine & Distributing Co. Examination revealed that 3 out of 126 of the articles were defective in that they contained holes.

LIBELED: 8–9–60, M. Dist. N.C.

CHARGE: 501(c)—while held for sale, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "To Be Used As A Preventive of Disease" was false and misleading as applied to a product which contained holes.

DISPOSITION: 9–23–60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

6431. Ulcertrol. (F.D.C. No. 42661. S. No. 47–135 P.)

QUANTITY: 42 12-oz. ctnd. btls. at White Pigeon, Mich., in possession of Ulcertrol, Inc.

SHIPPED: Two ingredients of the article, grapefruit juice and lemon juice, had been shipped on unknown dates from New York, N.Y., Davenport, Fla., and Ontario, Calif.

LABEL IN PART: "Ulcertrol A Completely New Ulcer Treatment * * * Made * * * of the following: Potatoe water, orange, lemon & grapefruit juices * * * Ulcertrol, Inc., White Pigeon, Michigan."

ACCOMPANYING LABELING: Leaflet enclosed in each carton entitled "*Ulcertrol.*"

RESULTS OF INVESTIGATION: The article was manufactured by the dealer at White Pigeon, Mich., using, among other ingredients, those ingredients which had been shipped in interstate commerce as described above.

LIBELED: 1–19–59, W. Dist. Mich.; amended 12–31–59.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers.

The article was alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: Ulcertrol, Inc., appeared as claimant and filed an answer. Thereafter, the Government served written interrogatories upon the claimant and, on 9–16–59, the claimant made certain replies to the interrogatories. Subsequently, motions were filed by the Government and granted by the court to compel further and complete answers to the interrogatories. Such answers were furnished by the claimant. On 9–8–60, a motion for summary judgment was filed by the Government. Such motion was not opposed by the claimant and, on 2–7–61, the court entered a decree of condemnation and destruction.

6432. Vita-Lea tablets, Pro-Lecin tablets, and Pro-Vita tablets. (F.D.C. No. 44680. S. Nos. 18–743/4 R, 19–071 R.)

QUANTITY: 21 180-tablet btls. of Vita-Lea; 15 180-tablet btls. and 12 360-tablet btls. of Pro-Lecin; and 5 pkgs. of 2 360-tablet btls. each, of Pro-Vita, at Delta, Colo.

SHIPPED: 5–1–60 and 6–10–60, from Oakland, Calif., by Shaklee Products.

LABEL IN PART: (Btl.) "Shaklee * * * Food Supplement With Digestive Enzymes * * * Vita-Lea;" "Shaklee * * * Pro-Lecin;" and (pkg.) "Shaklee Twin Pack Pro-Vita * * * Protein Vitamins Lecithin Minerals * * * Distributed by Shaklee Products, Oakland, Calif."

*See also Nos. 6421, 6422, 6425, 6426, 6428–6430.

ACCOMPANYING LABELING: Folders entitled "4 Aids to The Wealth of Health Through Better Nutrition" and "The Best Way to Health is Nature's Way."

LIBELED: 7–11–60, Dist. Colo.

CHARGE: 502(a)—when shipped, the labeling of "Vita-Lea" and "Pro-Vita" contained false and misleading representations that the articles were adequate and effective to produce buoyant and optimum health; "youth-time energy"; vitality; vigor; unlimited energy; zest for living; resistance to disease; good appetite; good personality; sound bones and teeth; proper construction of cells; strong blood; and vibrant living; and the labeling of "Pro-Lecin" contained false and misleading representations that the article was adequate and effective to produce the results alleged above for "Pro-Lecin" and "Pro-Vita" and in addition to control and prevent excessive cholesterol in the blood; heart attacks; strokes; and high blood pressure.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 9–6–60. Default—destruction.

6434. Metabolin capsules. (F.D.C. No. 44746. S. No. 41–197 R.)

QUANTITY: 1 50-lb. drum and 3 14-oz. btls. at Denver, Colo.

SHIPPED: The article was shipped in a bulk drum, on 3–23–60, from Decatur, Ill.

LABEL IN PART: (Drum) "Granular Lecithin Edible Soybean Phosphatides" and (btl.) "Glo-Way Chemical Co. * * * Lecithin * * * Granules From Soy Beans."

ACCOMPANYING LABELING: Booklet entitled "Lecithin and Health."

RESULTS OF INVESTIGATION: The 14-oz. bottles were packed by the dealer from the bulk stock shipped as described above.

LIBELED: 7–20–60, Dist. Colo.

CHARGE: 502(a)—while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for the prevention and treatment of diseases and conditions of the nervous system; glandular system; heart; kidney; liver; arteriosclerosis; deposits of cholesterol in the bloodstream; rheumatic carditis; coronary thrombosis; high blood pressure; anemia; diseases of the skin and hair; arthritis; diabetes; and mental ills; that it was capable of producing good health; healthier psyche; increased a feeling of well-being; longevity; resistance to virus infections; immunized against pneumonia; improved memory; increased hemoglobin count in the blood; promoted vigorous cell action and renewal of body cells.

The article was alleged also to be misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 9–6–60. Default—destruction.

6434. Metabolin capsules. (F.D.C. No. 44746. S. No. 41–197 R.)

QUANTITY: 874 100-capsule boxes at Litchfield, Ill.

SHIPPED: 5–19–58, 8–12–58, 9–4–58, and on an unknown date, from Atlanta, Ga. These were return shipments.

LABEL IN PART: "Metabolin * * * Each Metabolin Capsule contains: Natural Non-activated Carbon 200 mg. Pepsin USP 15 mg. Thiamin Mononitrate USP 2.5 mg. Riboflavin USP 3.0 mg. Niacin USP 20 mg. Iron from Natural Sources, and Ferrous Sulfate 17 mg. Selected, Dried, Processed, and Naturally Fermented Grains* (corn, wheat, milo and oats) 400 mg. * * * Directions * * * Distributed by Plopper's Laboratories, Inc., Litchfield, Illinois."

ACCOMPANYING LABELING: Leaflet in box entitled "Metabolin is the Natural Way."

LIBELED: 8-1-60, S. Dist. Ill.

CHARGE: 502(a)—when shipped, the name of the article was false and misleading since it suggested and implied that the article was capable of controlling the metabolic processes of the body whereas it was not capable of so doing; and the labeling contained false and misleading representations that the article was adequate and effective for the treatment and prevention of metabolic imbalance, tired, nervous, run-down feeling; irritable conditions; gastric distress and other discomforts of the stomach, such as flatulence, fullness, bloating, and stomach ulcers; anemia; and that it would build tissue, blood strength, restore strength, vigor, and well-being, and tone up nerves; that it was a source of vitality and vibrant good health; and that it was a treatment for "Metabolic Drag," a condition due to enzyme, vitamin B_1, vitamin B_2, and mineral deficiencies.

The libel alleged also that the article was misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 1-4-61. Default—destruction.

6435. **L6 tablets and Hemasthesia ointment.** (F.D.C. No. 44714. S. Nos. 30-590/2 R.)

QUANTITY: 400 55-tablet btls. of *L6 tablets* and 400 1¾-oz. tubes of *Hemasthesia ointment* at San Antonio, Tex., in possession of Alamo Medicine Co.

SHIPPED: 4-25-60 (*L6 tablets*) and during March 1960 (*Hemasthesia ointment*), from Bell Gardens, Calif.

LABEL IN PART: (Btl.) "L6 Tablets * * * Distributed by Alamo Pharmacal Co., San Antonio, Texas * * * Each Tablet Contains: Aspirin 2 gr., Sodium Salicylate 3 gr., Calcium Carbonate 1 gr., Calcium Ascorbate 10 mg., Para Amino Benzoic Acid 10 mg."; and (tube) "Hemasthesia Ointment For Hemorrhoids or Piles Contains: Benzocaine, Phenol, Boric Acid, Zinc Oxide, Bismuth Subnitrate, Resorcin, Balsam Peru in a special Ointment base."

ACCOMPANYING LABELING: Booklets entitled "That You May Live Again," "Arthritis and You!" and "Those Painful Hemorrhoids"; and form letters beginning "I am going to tell you something . . .," "Now, may I ask you a serious question?" and "If you are honestly seeking Help."

RESULTS OF INVESTIGATION: Investigation revealed that the dealer had reprinted the booklets with the authors' permission, had prepared the form letters, and had used the booklets and form letters in promoting sales of the tablets and ointment.

LIBELED: 7-25-60, W. Dist. Tex.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the tablets contained false and misleading representations that the article was capable of restoring lost strength, pep, energy and vigor to give one a new life of wonderful happiness and health; that use of the article would restore loss of sexual potency in men; that it was an adequate and effective treatment for pains in the lower part of the back and legs; and that the article was an adequate and effective treatment for all forms of arthritis and rheumatism; and the labeling which accompanied the ointment contained false and misleading representations that the article was an adequate and effective treatment for all forms of hemorrhoids or piles.

DISPOSITION: 9-27-60. Default—destruction.

6436. Honegar. (F.D.C. No. 44738. S. No. 31–172 R.)

QUANTITY: 132 1-pt. btls. and 41 1-qt. btls. at Houston, Tex., in possession of Foley's.

SHIPPED: 3–18–60 and 4–6–60, from Chicago, Ill., by B. T. Babbitt, Inc.

LABEL IN PART: (Btl.) "Undiluted Pure Honey * * * Apple Cider Vinegar * * * HONEGAR * * * Honegar Division, 625 Madison Ave., New York 22, N.Y."

ACCOMPANYING LABELING: Books entitled "Folk Medicine"; tag on pint bottle reading in part "A 'nature-wise' country doctor talks about * * * Folk Medicine by D. C. Jarvis M.D."; and counter display sign "Folk Medicine 'Honegar'—pure honey and apple cider vinegar—excellent health food."

RESULTS OF INVESTIGATION: Approximately 150 books as described above were displayed on a counter in the dealer's store at Houston, Tex., in conjunction with the counter display sign.

LIBELED: On or about 7–29–60, S. Dist. Tex.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for the treatment and prevention of arthritis, digestive disorders, belching, vomiting and diarrhea from food poisoning, constipation, obesity, high blood pressure, chronic fatigue and headaches, including migraine headaches, all infectious diseases, including typhoid, broncho-pneumonia, peritonitis, pleurisy, dysentery, fungus diseases, common cold, chicken pox, and measles, all childhood diseases, heart disease, heart attacks, essential hypertension, diabetes, insomnia, sterility, difficult labor, morning sickness, nervousness, tension, irritability, itching scalp and skin, numbness, cold hands and feet, dizziness, mental retardation, tooth decay, falling hair, breaking fingernails, paranasal sinusitis, seepage from sinuses, asthma, hay fever, facial neuralgia, retarded growth, pyelitis, thickened blood, ringing in ears, impaired hearing, Meniere's syndrome, callouses and corns, slow healing of cuts and bruises, pimples, tic, cramps in muscles, blocked and swollen lymph glands, cough, infant colic, bed-wetting, hangovers, alcoholism, and to provide vigor, promote longevity, maintain good health from the cradle to the grave, to control and reduce weight without restrictions of diet, and to reduce or eliminate the difficulties of old age; and 502(b)(1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 10–19–60. Default—destruction.

6437. Ul-C-Eze. (F.D.C. No. 44871. S. No. 30–897 R.)

QUANTITY: 432 3-oz. btls. at Jackson, Miss., in possession of L.C.Q. Drug Products Co.

SHIPPED: 6–29–60, from Worcester, Mass.

LABEL IN PART: "Ul-C-Eze * * * Active Ingredients: Bismuth Subgallate–Sodium Bicarbonate–Magnesium Trisilicate–Magnesium Hydroxide."

ACCOMPANYING LABELING: Placards reading in part "Ul-C-Eze * * * Antacid Powder" and "Your Customers Are Being Sold Ul-C-Eze"; leaflets entitled "Ul-C-Eze * * * Antacid Powder" and "Ul-C-Eze * * * Stomach Ulcer Sufferers."

RESULTS OF INVESTIGATION: The placards and leaflets were printed locally for the dealer and the article was manufactured for the dealer in Worcester, Mass.

LIBELED: 8–26–60, S. Dist. Miss.

CHARGE: 502(a)—while held for sale, the name of the drug "*Ul-C-Eze*" and the accompanying labeling contained false and misleading representations that the article was an adequate and effective treatment for stomach ulcers.

DISPOSITION: 10–12–60. Default—destruction.

6438. Virilon Physician's Formula and Virilon Hair Follicle Cleanser. (F.D.C. No. 45058. S. No. 32–446 R.)

QUANTITY: 43 8-oz. btls. and 96 ctns., each containing 6 4-oz. btls., of *Virilon Physician's Formula;* and 43 8-oz. btls. of *Virilon Hair Follicle Cleanser*, at Rochelle Park, N.J.

SHIPPED: 8–17–60 and 8–23–60, from Elmhurst, N.Y., by Steroid Products, Inc.

LABEL IN PART: (Btl.) "Virilon Physician's Formula For the Hair and Scalp * * * 20–X Steroid Products, Inc., 708 Pontiac State Bank Building, Pontiac, Michigan. Directions: For local use on the scalp. Contents: Lecithin, Cholesterol, Iso-cholesterol Lanosterol as esters; 20 mcg. Estradiol per ounce of alcohol (70% isopropyl). Patented by Robert Liefmann, M.D." and "Virilon Hair Follicle Cleanser * * *20–X Unique New Miracle hair follicle penetrant discovery! finest quality shampoo."

ACCOMPANYING LABELING: Steroid Products Salesmen's catalogs; sheets entitled "Mode of Application"; streamers entitled "Virilon Treatment For Beautiful Thick Hair & Healthy Scalp"; postcards reading in part "Dear Sir: Please send us free professional certificate of authorization . . ."; pamphlets entitled "Scalp Antizyme Treatment" for beauticians and "Scalp Antizyme Treatment" for barbers; display cards entitled "Doctor's Virilon Treatment"; reprints entitled "Secret Influence of Steroids" and "Biographical note on Robert Liefmann"; and counter display cartons entitled "Virilon Treatment."

LIBELED: 10–24–60, Dist. N.J.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the articles contained false and misleading representations that the articles were adequate and effective for the treatment of diseases of the hair and scalp, male-pattern baldness, excessive loss of hair, falling hair, scalp itch, dandruff, seborrhea; that use of the articles would restore hair to health and stimulate thick hair growth; that the articles were adequate and effective as a treatment for and preventive of facial blackheads, acne, old-age wrinkles; and that they would bring health to the skin and scalp; and 502(b)(2)—the labels of the articles failed to bear an accurate statement of the quantity of contents.

DISPOSITION: 11–28–60. Default—destruction.

6439. Dustronic Air Cleaner and Lectric Aire Negative Ionizer. (F.D.C. No. 45051. S. Nos. 45–101/7 R.)

QUANTITY: 8 cartoned *Dustronic Air Cleaner* devices, and 4 *Lectric Aire Negative Ionizer* devices, together with a number of charcoal filters used as a component part with some of the devices, at Seattle, Wash.

SHIPPED: The devices were shipped between 11–25–59 and 8–8–60, from Chicago, Ill., by Radex Corp., and the charcoal filters were shipped from Columbus, Ohio, by Barnebey-Cheney Co.

LABEL IN PART: (Devices) "Dustronic Lectric Aire Negative Ionizer [or "Dustronic * * * Air Cleaner"] * * * Radex Corp."; and (filter) "Dacor manufactured by Barnebey-Cheney Co. Columbus 19, Ohio. Dacor is the new

activated charcoal that removes odors–smoke–fumes and bacteria–SKF–16" x 25" x 1"."

ACCOMPANYING LABELING: Leaflets entitled "Instruction Sheet," "Increase Your Profit," and "Dustronic Air Cleaners"; catalogs entitled "Dustronic Air Filters"; charts entitled "Atmospheric Contaminants Chart"; reprints entitled "Dust-Free Air for Your Home," "What's as Rare," "Ozone has Fresh Air Smell," "How Much Ozone Can You Take?," "Ions Affect Health, Behavior," and "Negative Ions for Everybody"; booklets entitled "Lectric Aire" and "You Can Relieve Hay Fever and Asthma"; testimonial letters from "Meridian Brick Co.," "Park Ridge School," "Herald Express," and "The Cove Realty"; circulars entitled "Banish Air Pollution" and "Increase Your Profit"; testimonial letters from "Department of Chemistry"; reprints entitled "Beware of Ozone" and "Mechanical Maid"; circulars entitled "Dealers Profits from Pure Aire"; catalogs entitled "Housewives! Enjoy More Leisure Time"; circulars entitled "The Facts and Figures"; leaflets entitled "Enjoy a Cleaner, Fresher, Healthier Home"; price lists entitled "Dustronic Air Filters"; and circulars entitled "What Dustronic Means To You" and "Medical Benefits from Activated Charcoal Air Purification."

RESULTS OF INVESTIGATION: The devices consisted of various combinations of the following basic elements: a motor-driven fan, an aluminum mechanical filter, an electrostatic filter, a charcoal filter, a high voltage power supply, and a negative ion generator (tritium disc). In use the devices reportedly filtered the room air, subjected it to increased negative ions, and recirculated the air back into the room.

The circulars entitled "What Dustronic Means To You" were prepared by Joseph F. Taraba, Seattle, Wash., who was a distributor for the devices, and the circulars entitled "Medical Benefits from Activated Charcoal Air Purification" were obtained by the dealer from Barnebey-Cheney Co., Columbus, Ohio.

The other accompanying labeling was supplied by the Radex Corporation.

LIBELED: 10–21–60, W. Dist. Wash.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving hay fever, asthma, sinus, migraine headaches, avoiding common colds and removing bacteria, eliminating air-borne allergies, reducing respiratory disorders, viruses, and bacteria, collecting "more than 99% of ragweed pollen" and irritating agents, reducing pains of burns, reducing high blood pressure, improving mental attitude, arresting cancer growth, reducing arthritis and rheumatism, slowing aging process, and reducing fungus infection.

DISPOSITION: 2–6–61. Consent—claimed by Radex Corp., and relabeled.

6440. Pasitabs. (F.D.C. No. 44915. S. No. 44–175 R.)

QUANTITY: 25 cases, 24 18-tablet btls. each, and 1 case of 24 36-tablet btls., at Seattle, Wash.

SHIPPED: Between 8–8–60 and 8–29–60, from Los Angeles, Calif., by Retail Drug Service.

LABEL IN PART: (Btl.) "Pasitabs Has a Tranquilizer Action–An Aid to Relieve Excitability * * * Caltex Distributors Inc. * * * Each tablet contains: Sodium and Ammonium Bromides 4.75 gr., Niacinamide 5 mg. Thiamine HCl (Vit. B_1) 1 mg. in a specially prepared base containing Extract of Jamaica

Dogwood, Pleurisy Root, Glycyrrhiza Extract, Humulus, Lupulus, Valerian Root."

ACCOMPANYING LABELING: Display cartons reading "Pasitabs * * * The Wonderful Non-Habit Forming Tablets with the Tranquilizer Action"; window posters reading "Do You Have Jittery Nerves or Normal Nerves?"; and window streamers reading "Pasitabs * * * Tranquilizer * * * Relieve Excitability."

LIBELED: 9–28–60, W. Dist. Wash.; amended libel 10–4–60.

CHARGE: 502(a)—when shipped, the labeling of the article was false and misleading since it contained statements which represented and suggested that the article was a "tranquilizer," whereas it was not adequate and effective as a tranquilizer, and it was not a true tranquilizing drug; and the labeling also contained false and misleading representations that the article was an adequate and effective treatment for jittery nerves, nervous tension, nervous headaches, nervous stomach, emotional upsets, and that it could help steady and soothe jangled nerves, and relieve excitability.

DISPOSITION: 11–23–60. Default—destruction.

INDEX TO NOTICES OF JUDGMENT D.D.N.J. NOS. 6421 TO 6440

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U.S. GOVERNMENT PRINTING OFFICE: 1961

D.D.N.J., F.D.C. 6441–6460 Issued October 1961

U.S. Department of Health, Education, and Welfare

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

6441–6460

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce or while held for sale after shipment in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered by default, or by consent, and in one case by consent after compliance with a court order directing the claimant to supplement its answers to Government interrogatories; (2) criminal proceedings which were terminated upon pleas of guilty or nolo contendere; and (3) an injunction proceeding terminated upon the entry of a permanent injunction by consent. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D.C., *September 27, 1961.*

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*For omission of, or unsatisfactory, ingredients statements, See Nos. 6441, 6443; failure to bear a label containing an accurate statement of the quantity of the contents, No. 6443; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 6441, 6443, 6456; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 6449.

607045—61——1

SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6441–6460

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia or National Formulary), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its quality fell below that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; Section 502(c), the article failed to bear on its label or labeling, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e)(1), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling; Section 502(l), the article was composed wholly or in part of bacitracin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6441. Distilled water and hypodermic kits. (F.D.C. No. 45071. S. Nos. 31–110/2 R.)

QUANTITY: Unknown quantities of a clear liquid in unlabeled glass ampuls represented to be the *Koch Treatment*, and unknown quantities of hypodermic kits, each kit containing a glass hypodermic syringe and needle, at Palestine, Tex., in possession of Reynolds Clinic.

SHIPPED: On unknown dates from places outside the State of Texas.

ACCOMPANYING LABELING: Leaflets entitled "The Reynolds Clinic * * * Since 1941," "Koch's Glyoxylide 12X," "The Koch Treatment (Glyoxylide) in Alcoholic Neuritis * * * 3. Arthritis," "The Koch Treatment (Glyoxylide) in Alcoholic Neuritis * * * 2. Bursitis, Sciatica, Toxic Liver and Arthritis," "Order Form"; brochures entitled "Glyoxylide Case Reports" and "The Koch Treatment Patients Diet"; and a mimeographed slip of paper reading in part "Glyoxylide 12X Sterile * * * O=C=C=O."

LIBELED: 11–2–60, E. Dist. Tex.

CHARGE: *Clear liquid in ampuls.* 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that

the article was adequate and effective in the treatment and prevention of cancer and other diseases and conditions in man; 502(b)(1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—the label of the article failed to bear the common or usual name of the article, namely, *distilled water;* 502(f)(1)—the label of the article failed to bear adequate directions for use in that the directions for use with respect to dosage and frequency and duration of administration of the article were not adequate for the treatment or prevention of the diseases and conditions for which the article was intended, including in particular, cancer; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was in the possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs, and since the article was not to be dispensed upon prescription; 502(f)(2)—the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of administration; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its label.

Hypodermic kits. 502(f)(1)—the labeling of the article failed to bear adequate directions for use; 502(f)(2)—the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of application; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its labeling.

DISPOSITION: 1–4–61. Default—delivered to the Food and Drug Administration.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

6442. Bacitracin. (F.D.C. No. 45072. S. Nos. 32–340 R, 32–451 R, 33–362/4 R, 36–101/2 R.)

QUANTITY: 734 ctnd. vials at New York, N.Y.

SHIPPED: Between 8–11–60 and 8–16–60, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LABEL IN PART: (Ctn. and ampul) "No. 2005 Bacitracin U.S.P. Sterile 50,000 Units For Intramuscular or Topical Use * * * Philadelphia Ampoule Laboratories, Philadelphia 23, Pa. * * * Lot No. 8018 Exp. Date 9–62."

LIBELED: 11–16–60, S. Dist. N.Y.

CHARGE: 501(b)—when shipped, the strength of the article differed from the strength set forth in the United States Pharmacopoeia for *bacitracin;* 502(a)—the label statement "50,000 Units" was false and misleading as applied to a product containing less than 50,000 units of *bacitracin* per ampul; and 502(l)—the article purported to be, and was represented as, a drug composed wholly or in part of *bacitracin,* and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 12–27–60. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6443. Dextro-amphetamine sulfate tablets, pentobarbital sodium capsules, and dextro-amphetamine sulfate with amobarbital tablets and capsules. (F.D.C. No. 45323. S. Nos. 29–662/4 R, 53–597 R, 53–600 R.)

QUANTITY: 5 1,000-tablet btls. of dextro-amphetamine sulfate with amobarbital, 3 1,000-tablet btls. and 7 200-tablet bags of dextro-amphetamine sulfate, 1 700-capsule btl. of pentobarbital sodium, and 1 btl., containing 541 capsules of dextro-amphetamine sulfate with amobarbital, at Minneapolis, Minn., in possession of Cedar Drug Co.

SHIPPED: On unknown dates, from outside the State of Minnesota.

LIBELED: 1–4–61, Dist. Minn.

CHARGE: 502(b)—while held for sale, all of the articles failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the label of the 7-bag lot failed to bear the common or usual name of the drug; 502(f)(1)—the label of the 7-bag lot failed to bear adequate directions for use; and 503(b)(4)—the label of the 7-bag lot failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 2–16–61. Default—destruction.

DRUGS AND DEVICE ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6444. Food supplements. (F.D.C. No. 44330. S. Nos. 52–117/8 P.)

INFORMATION FILED: 7–20–60, Dist. Minn., against Arthur W. Stemper, t/a A. & N. Stemper Co., and Mrs. Arthur W. Stemper.

ALLEGED VIOLATION: On 7–16–59, in a sales talk at Minneapolis, Minn., the defendants orally represented the articles to persons there present to be an effective treatment for the diseases, symptoms, and conditions set forth below, which act resulted in the articles being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: "A Complete Balanced Food Supplement NUTRITION-ALL Proteins—Minerals—Vitamins," and "NUTRITION-ALL High protein."

CHARGE: 502(f)(1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the articles were intended, namely, low and high blood pressure, bad nerves, bursitis, cancer, poor eyesight, rare blood condition, diabetes, and arthritis.

PLEA: Guilty.

DISPOSITION: 11–14–60. Each defendant was fined $100 and placed on probation for 2 years.

6445. Nutrin vitamin and mineral capsules. (F.D.C. No. 44344. S. No. 66–601 P.)

INFORMATION FILED: 7–26–60, W. Dist. Pa., against Chester H. Nairne, t/a Chester H. Nairne Co., Niles, Ohio.

ALLEGED VIOLATION: Between 10–22–59 and 10–29–59, the defendant, in the course of sales talks at Pittsburgh, Pa., made oral representations holding

*See also Nos. 6441, 6443.

out *Nutrin vitamin and mineral capsules* as a treatment and preventive for the diseases, symptoms, and conditions set forth below, which acts resulted in the article being misbranded under 502(f)(1) while held for sale after shipment in interstate commerce.

The information alleged also that the defendant caused a leaflet entitled "Nutrin When Food Alone is not enough Nutrin Capsules" to accompany the article as labeling, which act resulted in the article being misbranded under 502(a) while held for sale after shipment in interstate commerce.

LABEL IN PART: (Btl.) "NUTRIN Multi-Vitamins & Minerals Each capsule contains: Vitamins Vit. A (Fish Liver Oil) 5000 USP units Vit. D (Irradiated Ergosterol) 1000 USP units Vit. B–1 (Thiamine Hydrochloride) 3 mg. Vit. B–2 (Riboflavin) 2.5 mg. Vit. B–12 1.5 mcg. Vit. B–6 (Pyridoxine Hydrochloride) 0.75 mg. Vit. C (Ascorbic Acid) 50 mg. Niacinamide 20 mg. Calcium Pantothenate 5 mg. Folic Acid 0.34 mg. Vit. B (as d-alpha Tocopheryl Acetate) 3 int. units Minerals Calcium 215 mg. Iron 13.4 mg. Phosphorous 166 mg. Potassium 5 mg. Iodine 0.1 mg. Manganese 1.5 mg. Sulphur 10 mg. Cobalt 0.1 mg. Molybdenum 0.4 mg. Zinc 1.4 mg. Copper 1 mg. Magnesium 7.5 mg. 30 Capsules Distributed by CHESTER H. NAIRNE CO. 70 Tenth St. Niles, Ohio."

CHARGE: 502(a)—the leaflet which accompanied the article as labeling contained false and misleading representations that the article was adequate and effective for producing perfect health, active brain, steady nerves, happy disposition, strength, vigor, unlimited energy, sturdy growth, and good bones and teeth; that the article was adequate and effective for the regulation of nervous and muscular activity, coagulation of the blood, proper functioning of the heart, muscles, nerves and body tissues, counteraction of acids, healing of wounds, strengthening of mental power, regulation of all of the nutritive processes, prevention of goiter, purifying the system, and regenerating the body by purifying the blood; and that the food supplies generally available are nutritionally deficient and inferior and lack sufficient amounts of the vitamins and minerals for normal nutrition; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use in the treatment and prevention of the diseases, symptoms, and conditions for which the article was intended, namely, the treatment and prevention of sinusitis, catarrh, neuralgia, bursitis, rheumatism, lumbago, sciatica, gout, arthritis, poor eyesight, premature death, obesity, underweight conditions, nervous breakdown, sleeplessness, tiredness, indigestion, heartburn, irregular bowel movements, nervous strain, poor teeth, half dead feeling, irritability in children, heart disease, diabetes, and colds, for the prevention of tonsillitis, polio, appendicitis, gallstones, and kidney stones, for the treatment of the thyroid and parathyroid glands, and reduced sexual powers, which were the diseases, symptoms, and conditions for which the article was held out to the persons present at the aforesaid sales talks.

PLEA: Nolo contendere.

DISPOSITION: The case was transferred to the United States District Court for the Eastern District of Michigan for the entry of the above-mentioned plea and, on 1–10–61, such court fined the defendant $500.

6446. Figurama device. (F.D.C. No. 42015. S. No. 21–868 P.)

QUANTITY: 12 devices at Kansas City, Mo., in possession of AAA Distributing Corp.

SHIPPED: Between 6–12–58 and 8–5–58, from Midland, Conn., by Streamform Corp.

LABEL IN PART: (Metal plate on device) "Figurama Streamform Corp. New York, N.Y."

ACCOMPANYING LABELING: Cards designated "Complimentary Invitation"; a folder designated "Figurama"; and an advertising mat designated "Reduce at Home."

RESULTS OF INVESTIGATION: The article was a streamlined box-like metal device equipped with coasters and enclosing a vibrating motor. The device was equipped with two upholstered massage pads and tubular cot-like attachments for conversion for use in a reclining position.

LIBELED: 9–10–58, W. Dist. Mo.

CHARGE: 502(a)—when shipped and while held for sale, the name of the device "Figurama" and the labeling accompanying the device contained false and misleading representations that the device was an adequate and effective treatment for reducing weight, correcting poor posture, firming and toning the body and providing a greater sense of well-being; and 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of nervous tension and diabetes, improving elimination and circulation, and treatment of a heart condition due to nervous tension, which were the purposes for which the device was offered orally by a sales representative on the premises of the dealer.

DISPOSITION: Streamform Corp. appeared as claimant and upon stipulation of the parties, the case was removed to the United States District Court for the District of New Jersey. The claimant then served written interrogatories upon the Government which were answered. Thereafter, the Government served the following written interrogatories upon the claimant:

"The United States of America, libellant herein, by Chester A. Weidenburner, United States Attorney for the District of New Jersey, submits the following written interrogatories pursuant to Rule 33 of the Federal Rules of Civil Procedure:

"1. Give the name and address of the person or firm that manufactured the seized devices, and the date and place of manufacture.

"2. State when the seized devices were introduced into interstate commerce, the name and address of the person or firm who introduced them into interstate commerce, the name and address of the carrier involved, the name and address of the person or firm to whom the devices were delivered and the date of delivery.

"3. State on what date and in what manner the claimant became the owner of the seized devices.

"4. Give the name and address of the person or firm who prepared the cards entitled 'Complimentary Invitation,' the folders designated 'Figurama' and the advertising mats designated 'Reduce at Home.'

"5. State how the aforementioned cards, folders and advertising mats were packed or located in relation to the devices referred to.

"6. If it is alleged in answer to interogatory 5 that the cards, folders and advertising mats, or any of them, were not physically attached to the devices, state where the said cards, folders and advertising mats were located on the premises of AAA Distributing Corp. with relation to the said devices.

"7. Set forth a copy of the aforementioned cards, folders and advertising mats.

"8. State the relationship which claimant has with respect to AAA Distributing Corp.

"9. Does claimant admit that the seized devices are not an adequate and effective treatment:

(a) For reducing weight.
(b) For correcting poor posture.
(c) For firming and toning the body.
(d) Providing for a greater sense of well being.

"10. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response, provide in detail the facts which claimant contends to be true and the names and addresses of all physicians and others having knowledge of such facts.

"11. Is it claimant's position that the seized devices are an adequate and effective treatment:

(a) For reducing weight.
(b) For correcting poor posture.
(c) For firming and toning the body.
(d) Providing for a greater sense of well being.

"12. Does claimant admit that nowhere in the aforementioned cards, folders, and advertising mats or on any imprinting or printing on the devices themselves, is there any statement that the devices are to be used:

(a) In the treatment of nervous tension.
(b) In the treatment of diabetes.
(c) To improve elimination and circulation.
(d) For treatment of a heart condition due to nervous tension.

"13. Does claimant admit that no other written, printed or graphic matter on the premises of AAA Distributing Corp. contained statements representing that the devices are to be used:

(a) In the treatment of nervous tension.
(b) In the treatment of diabetes.
(c) To improve elimination and circulation.
(d) For treatment of a heart condition due to nervous tension.

"14. Does claimant admit that there is no written, printed or graphic matter relating to use of the seized device which suggests its use:

(a) In the treatment of nervous tension.
(b) In the treatment of diabetes.
(c) To improve elimination and circulation.
(d) For treatment of a heart condition due to nervous tension.

"15. Does claimant admit on August 7, 1958, on the premises of AAA Distributing Corp., 3303 Troost, Kansas City, Missouri, the seized devices were offered orally by a sales representative on the premises of the aforementioned firm for:

(a) Treatment of nervous tension.
(b) Treatment of diabetes.
(c) Improvement of elimination and circulation.
(d) Treatment of a heart condition due to nervous tension.

"16. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such response provide in detail the facts which claimant contends the true facts to be and the names and addresses of all persons having knowledge of such facts.

"17. Does claimant admit that on September 11, 1958, the United States Marshal for the Western District of Missouri, pursuant to monition, seized 12 Figurama devices, 12 advertising mats, 22 invitations, and 155 folders of

'Figurama' on the premises of, and in possession of AAA Distributing Corp. and/or Raymond A. Thomas, 3303 Troost, Kansas City, Missouri?

"18. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"19. Does claimant admit that the devices, advertising mats, cards, and folders were shipped by Streamform Corp., Midland, Connecticut, on or about one or more of the following dates: June 12, July 3, July 21 and August 5, 1958.

"20. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"21. Does claimant admit that the mats, cards, and folders relate to use of the seized devices.

"22. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"23. Does claimant admit that the mats, cards and folders were on the same premises as the devices?

"24. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"25. Does claimant admit that the copies of the mats, cards and folders, attached as part of Government's response to claimant's interrogatories, are true and accurate copies of the seized counter-parts.

"26. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true and the names and addresses of all persons having knowledge of such facts.

"27. Give the name and address of the printers who made up the mats, cards and folders.

"28. Give the dates and the names and addresses of the persons or firms from whom AAA Distributing Corp. received:

(a) The seized devices.
(b) The advertising mats.
(c) The cards.
(d) The folders.

"29. Does claimant admit that the seized devices are intended to be used for:

(a) Reducing weight.
(b) Correcting poor posture.
(c) Firming and toning the body.
(d) Providing for a greater sense of well being.

"30. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other response provide in detail the facts which claimant contends to be true, the names and addresses of all persons having knowledge of such facts, and a complete description of each and every purpose, disease, or condition for which the seized devices are intended to be used.

"31. Does claimant admit that the cards, mats and folders recommend and suggest that the devices are to be used for:

(a) Reducing weight.
(b) Correcting poor posture.
(c) Firming and toning the body.
(d) Providing for a greater sense of well being.

"32. If any portion of the response to the preceding interrogatory is anything other than an unqualified affirmative response, then for each such other

response provide in detail the facts which claimant contends to be true, the names and addresses of all persons having knowledge of such facts, and a complete description of each and every purpose, disease, or condition which the cards, mats and folders recommend and suggest that the devices are to be used.

"33. Name and provide a complete description for each and every purpose, condition or disease for which claimant contends the seized device is an adequate and effective treatment.

"34. For each purpose, condition, or disease enumerated in answer to the preceding interrogatory provide:

(a) The names, addresses and professional qualifications of all physicians or other scientists who have knowledge of such facts.
(b) The names and addresses of all other persons who have knowledge of such facts.
(c) Citations to all medical or other scientific literature which supports such facts.

"35. Name and provide a complete description, for each and every purpose, condition or disease for which the seized device is beneficial.

"36. For each purpose, condition, or disease enumerated in answer to the preceding interrogatory provide:

(a) The names, addresses and professional qualifications of all physicians or other scientists who have knowledge of such facts.
(b) The names and addresses of all other persons who have knowledge of such facts.
(c) Citations to all medical or other scientific literature which supports such facts.

"37. For each and every purpose, condition or disease enumerated in response to interrogatories 30, 32, 33, 35, give the names, addresses, and professional qualifications of all experts qualified by training and experience to evaluate the efficacy of the seized device upon whose opinion the claimant has relied, or now relies, in making each such response.

"38. State the name and address of the designer or inventor of the seized devices.

"39. State whether the device is patented.

"40. If interrogatory No. 39 is answered affirmatively, give the patent number and state the name and address of the person or firm who holds the patent.

"41. List all component parts of the device under seizure and state the purpose of function of each part in the operation of the device.

"42. (a) Since the original model of this device was first manufactured and distributed, what alterations have been made on it?
(b) Explain why such changes were made.
(c) State the operating principle by which the device accomplishes its intended purpose(s).

"43. (a) How does the manufacturer of the device determine whether it conforms to specifications after it is assembled?
(b) How is it tested in the factory?

"44. Does the device have Underwriters approval?

"45. (a) Is the patient protected against electrical shock from the device?
(b) How?

"46. What is the name and the address of the insurance firm with whom claimant maintains products liability insurance?

"47. (a) List the names and addresses of all persons or firms who registered complaints about Figurama with claimant since the inception of business.
(b) Give the names and addresses of all Figurama purchasers to whom claimant has made refunds and state the reason for each refund.

"48. (a) State whether Figurama is now being used or has been used in any hospitals or other medically supervised institutions.
(b) State whether claimant ever delivered a Figurama device to any hospitals or other medically supervised institutions.

"49. If interrogatory 48 is answered affirmatively, state the names and addresses of the institutions and the names and titles of the person or persons acquainted with its use.

"50. Set forth the complete directions for use in using this device for:

(a) The treatment of nervous tension, diabetes; improvement of elimination and circulation; and treatment of a heart condition due to nervous tension.
(b) To resize the figure and improve the posture; to remove an inch or more off hips, waist, tummy within minutes. To trim and acquire fashionable slenderness without disrobing, without drudgery, drugs, or strenuous diet.
(c) For figure improvement, figure reducing, and posture improvement as associated by the claimant with the word Figurama.

"51. Set forth copies of all the directions referred to in interrogatory No. 50 and state how all these directions reach the patient.

"52. Give the names, addresses, and professional qualifications of all experts qualified by training and experience to evaluate the efficacy of the said device upon whose opinion the claimant has relied, or now relies, to support its claim that the device is adequate and effective for:

(a) Reducing weight.
(b) Correcting poor posture.
(c) Firming and toning the body.
(d) Providing for a greater sense of well being.

"53. Provide citations to all scientific literature of which claimant is aware which deals specifically with the efficacy of the seized device or its components and any other similar device.

"54. State if claimant has conducted or has had conducted, or knows of any tests or studies which have been conducted or are being conducted to determine the efficacy of the device under seizure.

"55. If the response to interrogatory No. 54 is in the affirmative, state in detail for each such test or study:

(a) The number of such tests or studies that have been conducted indicating the number of clinical tests or studies, the number of laboratory tests or studies.
(b) A detailed description of the method or procedure employed by each study or test and the results obtained.
(c) The names, addresses, and qualifications of all individuals conducting or participating in the conduction of each such study or test.
(d) The location and name of the clinic, office, institution, laboratory, or building where such tests or studies were conducted.
(e) The name and address of each test subject and the name and address of each control subject used in

such test or study, designating which were test and which were control subjects and the exact condition of each subject, giving complete information concerning the severity, duration, and origin of such condition or disease.

(f) The name, address, and qualifications of each of the physicians who diagnosed each of the test and control subjects prior to and during the test or study.

(g) The frequency, duration time, and method of use of the Figurama device by each subject and the complete description of all the treatments administered to each subject.

(h) The nature, extent, and duration of improvement or deterioration of each of the subject's condition, subsequent to the test or study and for each subject give the name and the address and qualifications of the physician who diagnosed subject's condition, subsequent to the test or study.

(i) The name and the address of the place where the charts, records, and reports of the test or studies are located.

(j) The name and address of the person or persons in whose possession or custody are these charts, records, and reports.

(k) If any such tests or studies are now in progress, please so indicate, and provide as much information in the response to this interrogatory as is now in existence.

"56. (a) State whether clinical measurements have been done to determine the relaxing tension effect of this device.

(b) If the response to (a) above is in the affirmative, provide answers to 55 (a)-(k) at this point with respect to such measurements.

"57. Describe in detail the separate vibratory motions ascribed to this device by claimant.

"58. (a) State whether any type of measurements have been made to determine the depth of the penetration in the body of the vibrations produced by this device.

(b) If the response to (a) above is in the affirmative, provide answers to 55 (a)-(k) at this point with respect to such measurements.

"59. (a) State whether any scientific studies have been done to show that the muscles in the body are affected by the vibratory motions.

(b) If the response to (a) above is in the affirmative, provide answers to 55 (a)-(k) at this point with respect to such measurements.

"60. Referring to the labeling exhibits attached to libelant's answers to claimant's interrogatories, what is meant by:

(a) 'Figurama restores nature's line of figure beauty.'
(b) 'Slenderizing.'
(c) 'Figurama.'
(d) 'Figurama firms and tones the body as it reproportions your figure.'
(e) 'reducing at home.'
(f) 'see the first inch (or more) vanish.'

(g) 'prove that you, too, can have and hold a beautiful figure.'
(h) 'perfected by world-famous reducing authority, Monty MacLevy.'

"61. (a) Give the full name and address of Monty MacLevy.
(b) State in detail his position and responsibilities in the claimant firm.
(c) What scientific studies using the device under seizure has Monty MacLevy conducted and where were they published?
(d) What are the means of conveying to the patient the directions for use of the device as formulated by Monty MacLevy. Set forth such directions.

"62. State the names, addresses, and professional qualifications of all experts with whom the claimant has conferred about the labeling made for this device.

"63. Give citations to all the scientific literature to which claimant has referred in preparing the labeling claims for this device.

"64. (a) State the names and addresses of any newspapers, magazines, journals, or other publications in which claimant has placed advertisements or comments regarding the Figurama device and dates of each.

"65. (a) State whether claimant knows of any scientific data, or has knowledge of any studies made in which the various etiological causes of the overweight were determined in overweight patients using the Figurama device.
(b) If so give citations to or set forth the scientific data and with respect to any such studies provide answers to interrogatory 55 (a)–(k).

"66. (a) State whether claimant knows of any scientific data, or has knowledge of any studies made in which the various etiological causes of the nervous tension were determined in the patients using the device for nervous tension.
(b) If so give citations to or set forth the scientific data and with respect to any such studies provide answers to interrogatory 55 (a)–(k).

"67. (a) State whether claimant knows of any scientific data, or has knowledge of any studies made in which the various etiological causes of poor posture were determined in the patients using the device for poor posture.
(b) If so give citations to or set forth the scientific data and with respect to any such studies provide answers to interrogatory 55 (a)–(k).

"68. State the names and addresses of witnesses whom claimant now intends to call at the trial of this case."

The claimant filed objections to a number of the interrogatories submitted by the Government and, on 5–26–59, after consideration of the arguments of counsel, the court handed down the following decision:

WORTENDYKE, *District Judge:* "On September 11, 1958, the Government filed a Libel in the Western Division of the Western District of Missouri against 'TWELVE DEVICES, MORE OR LESS, LABELED IN PART (METAL PLATE ON FRONT OF DEVICE) "FIGURAMA STREAMFORM CORP. NEW

YORK, N.Y." (METAL PLATE ON BACK OF DEVICE) "* * * SERIAL NO. * * * MODEL NO. * * *" and TWO HUNDRED CARDS, MORE OR LESS, DESIGNATED "COMPLIMENTARY INVITATION," 1 OR MORE FOLDERS DESIGNATED "FIGURAMA," and 1 OR MORE ADVERTISING MATS DESIGNATED "REDUCE AT HOME," ' in possession of AAA Distributing Corporation, 3303 Troost, Kansas City, Mo., for alleged misbranding while in and while held for sale after shipment in interstate commerce within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 352(a). Responsive to Monition duly issued, Streamform Corp., a New York corporation, filed notice of claim to the libeled articles and by stipulation between respective counsel for libellant and claimant, the action was removed to the United States District Court for the District of New Jersey.

"The libel charges that the term 'Figurama' in the labeling of the device, together with the 'Complimentary Invitation' cards, 'Figurama' folders, and advertising mats designated 'Reduce at Home' represent and suggest that the device is an adequate and effective treatment for weight reduction, posture correction, firming and toning the body and enhancing the sense of well-being, which statements are false and misleading.

"To certain of the sixty-eight written interrogatories propounded by the libellant, claimant has filed objections, and a hearing upon these objections was held May 25, 1959, pursuant to due notice. A classification of the interrogatories objected to, the grounds for the objections, and my decision thereon, are as follows:

Interrogatories numbered 5, 6, 23 and 24: Information sought is peculiarly within the knowledge of libellant.

"Because a critical question in the case is the relationship between the device itself and the cards, folders and advertising mats, the information sought by this group of interrogatories objected to becomes highly relevant. Even if that information is already known to or has previously been obtained by libellant, claimant may be compelled to furnish the information to libellant if it is available to the claimant. The information is not only relevant to the subject matter of the action, but relates to the claim of the examining party. Rules 33 and 26(b). These interrogatories must be answered.

Interrogatories numbered 15 and 16: Information sought concerns oral statements made by third party out of presence of claimant.

"Claimant objects to these two interrogatories because they seek an admission by claimant of oral representations made by a sales representative of the distributor of the device. While such an admission could be sought under Rule 36, it is equally susceptible under Rule 33. If the answer to interrogatory number 15 is 'No' (a refusal to admit), interrogatory number 16 becomes proper since it invites claimant's version of the 'true facts' constituting the subject matter of interrogatory number 15. If, on the other hand, the answer to any of the subdivisions of interrogatory number 16 is unqualifiedly 'Yes' then number 16 need not be answered with respect to that subdivision, but it is an appropriate interrogatory with respect to the remaining subdivisions of interrogatory number 15. Both of these interrogatories, therefore, should be answered.

Interrogatory number 27: Irrelevance of names and addresses of printers who made the cards, mats and folders.

"The name and address of each of the printers who made the mats, cards and folders is information to which libellant is entitled. It is relevant to the subject matter involved in the action and appears to be reasonably calculated to lead to the discovery of admissible evidence thereon. This interrogatory should be answered.

Interrogatories numbered 29, 30, 31 and 32: Information sought is to be found in the labeling and printed material complained of.

"These interrogatories are proper for the same reasons which support the propriety of numbers 15 and 16 above. These four interrogatories should therefore be answered.

Interrogatories numbered 33, 34, 35, 36 and 37: Irrelevance of information sought.

"Claimant's objection to this group of interrogatories is not well founded. For example, if the device may not be effectively used in the treatment of condition A, claimant's assertion that it may be effectively used in condition B may not only relate to the defense of the claimant, but negate the effectiveness of the device for the treatment of condition A. In their remotest aspect, the answers to the inquiries contained in this group of interrogatories may serve to sustain the charges contained in the libel. They should be answered.

Interrogatories numbered 38, 39, and 40: Irrelevance of information sought.

"The objection to these three interrogatories is based upon the contention that the information sought thereby is irrelevant. Libellant seeks the identity of the inventor of the device and information respecting its patenting. This information is highly relevant to the subject matter of the inquiry because the patent and its file wrapper may constitute relevant evidence upon the question of the effectiveness of the device for any of the purposes alleged to have been represented by the claimant. These interrogatories must be answered.

Interrogatories numbered 42(a) and 42(b): Irrelevance.

"These two subdivisions of interrogatory number 42, as well, are entirely relevant because any changes which may have been made in the device between the date of the issuance of a patent thereon and the date of the alleged misbranding, relate directly to the critical issue presented by the misbranding charge. These should also be answered.

Interrogatories numbered 43, 44 and 45: Irrelevance.

"Because one of the objectives of the Act is the protection of the consuming public, I consider interrogatories numbered 44 and 45 relevant and proper; but number 43, in my opinion, is irrelevant and improper. Numbers 44 and 45, therefore, should be answered.

Interrogatory number 46: Irrelevance.

"This interrogatory seeks the name and address of claimant's products liability insurance carrier. This need not be answered because it is irrelevant.

Interrogatories numbered 47(a) and 47(b): Irrelevance.

"This interrogatory seeks the names and addresses of purchasers of the device who have complained about it and sought a refund of the purchase price. Information responsive to this interrogatory may lead to evidence supportive of libellant's charges and hence it should be answered.

Interrogatories numbered 52, 54, 55, 56, 58, 59, 65, 66 and 67: Information sought is result of work performed by experts shielded from interrogation, and may be readily obtained by libellant.

"The objection to this group of interrogatories is induced by the reluctance of claimant to disclose the products of its experts. Upon the authority of *Sachs* v. *Aluminum Company of America*, 6 Cir. 1948, 167 F. 2d 571, the product of such experts is not privileged matter. These interrogatories should also be answered.

Interrogatory number 60: Labeling speaks for itself.

"This interrogatory is clearly relevant to the issue of labeling. It seeks claimant's meaning and intent in the use of the words and phrases employed in the labelling exhibits referred to. It must be answered.

Interrogatory number 64: Irrelevance.

"I agree with claimant that the information sought by this interrogatory is not relevant to the charges laid in the libel. This interrogatory need not be answered.

"An order in conformity with this opinion may be presented."

The claimant thereafter submitted certain answers to the Government's interrogatories, after which the Government filed a motion to compel the claimant to make further and more adequate answers to the interrogatories. On 9–17–59, the court advised counsel for the parties of its decision in the matter by letter which reads as follows:

WORTENDYKE, *District Judge:* "This letter will serve to embody my decision upon the motion of the libellant, United States of America, to compel further and more complete answers to written interrogatories propounded by it to claimant, Figurama Streamform Corp. At the conclusion of the oral argument on September 14, 1959 I undertook to examine the motion papers, together with the memoranda submitted by the respective parties, and determine the questions presented within the next succeeding few days. My determination is, therefore, as follows (the successive numbers referring to the interrogatories and answers to which libellant's motion is directed):

"5. Answer should disclose information obtained and efforts made to obtain information from AAA Distributing Corp.

"6. State all responsive facts, rather than incorporating by reference matter of allegation presently expressed in No. 5.

"10. State as fact, rather than as an allegation, all matter responsive to the question and give the names and addresses requested.

"13. Answer categorically Yes or No to each subdivision.

"16. Disclose fully all facts and the names and addresses of persons sought by this question.

"17. Answer categorically Yes or No.

"18. Answer with full responsiveness if the answer to No. 17 is not Yes.

"19. This answer is sufficient.

"20. Answer with full responsiveness in view of the negative answer to No. 19.

"22. Answer this with full responsiveness in view of the negative answer to No. 21.

"23. This should be answered Yes or No.

"24. Answer with full responsiveness if answer to No. 23 is not Yes.

"25. This should be answered Yes or No.

"26. Answer with full responsiveness if answer to No. 25 is not Yes.

"32. Answer with full responsiveness with relation to any of the subdivisions of interrogatory No. 31 not answered affirmatively.

"33. Answer with full responsiveness.

"34. Answer with full responsiveness.

"35. Answer with full responsiveness.

"36. Answer with full responsiveness.

"37. Answer with full responsiveness.

"38. The answer to this interrogatory is sufficient.

"47(a). Secure the information sought and set it forth in a fully responsive answer.

"48. Answer each subdivision with full responsiveness upon the assumption that the interrogatory refers to ALL or ANY Figurama products.

"49. Depending upon the answers to the subdivisions of interrogatory No. 48, answer interrogatory No. 49 responsively.

"50(b). This must be answered responsively. If no directions for use for such purposes, so state.

"50(c). This must be answered responsively. If no directions for use for such purposes, so state.

"52. Answer this interrogatory responsively.
"54. The answer to this interrogatory is sufficient.
"55(a) through 55(k). Answer this interrogatory and its subdivisions responsively, since the answer to interrogatory No. 54 discloses that tests are being conducted.
"56. Answer this interrogatory responsively in view of the answer to interrogatory No. 54.
"60. Answer each of the subdivisions of this interrogatory responsively by defining the words and phrases respectively therein set forth, irrespective of the claimant's denial that the exhibits referred to constitute labelling.
"61(a). The answer to this sub-interrogatory is adequate.
"61(d). Amplify this answer, irrespective of the description of the users of the device as patients.
"62. Answer this interrogatory responsively, irrespective of claimant's denial.
"63. This interrogatory should be answered responsively irrespective of claimant's denial.
"65. Answer this interrogatory responsively, irrespective of the reference to users as patients.
"66. Answer each of the subdivisions of this interrogatory, responsively, without reference to the answer to any other interrogatory.
"67. Answer each of the subdivisions of this interrogatory, irrespective of the designation of the device users as patients.
"An appropriate order embodying my determination as aforesaid may be presented after submission to adversary counsel for approval as to form."

In accordance with the views expressed by the court in its letter of 9–17–59, an order was entered by the court on 9–24–59 directing the claimant to amplify its answers. The claimant thereupon submitted supplemental answers. The Government subsequently asserted that the answers were insufficient and filed a motion for default judgment. On 12–8–59, the court handed down the following opinion in the matter:

WORTENDYKE, *District Judge:* "In this action, instituted under the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, et seq., seizure was made of the articles indicated in the caption, to which claim was duly made by answer filed, charging misbranding of the device referred to by reason of failure of compliance with the provisions of § 352(f)(1). The Government prayed condemnation of the devices, including the cards, folders and advertising mats accompanying the same, all of which had been introduced into, were in, and were being held for sale after shipment in interstate commerce.

"In due course claimant served interrogatories upon libelant, which were responsively answered. Thereafter libelant served interrogatories upon counsel for claimant. These included some sixty-eight questions, several of which contained numerous subdivisions. To these interrogatories claimant served objections and noticed hearing thereon, after which the Court, by directive of June 5, 1959, ordered that all of the Government's interrogatories be answered except those numbered 46 and 64 respectively. Claimant proffered purported compliance with the Court's order by serving certain answers to the interrogatories with which the Government was not satisfied. Libelant thereupon moved for an order requiring claimant to make more specific answers to certain of its interrogatories, and, on September 24, 1959, after a hearing upon such motion, claimant was ordered to amplify its answers to conform with the views expressed in the Court's letter to counsel dated September 17, 1959. Again by way of response to the Court's latest order, claimant further supplemented its answers. Once more asserting the insufficiency of these latest supplementary answers, the Government noticed a motion for judgment of default in favor of libelant. The particular answers of the inadequacy of which the Government still complains are those respectively to libelant's interrogatories numbered 55, 10, 22, 34 (a), (b) and (c), 36 (a), (b) and (c), 37, 52 and 63.

"While there is ample authority to penalize claimant's apparent unwillingness to answer certain of the interrogatories which the Court has found proper

and which its prior orders required to be answered—*United States* v. *42 Jars, etc. Bee Royale Capsules*, 3 Cir. 1959, 264 F. 2d 666, F.R.C.P. 37(b)(2)(iii)—the drastic nature of such a penalty makes the Court reluctant to apply it if other relief may possibly be available. The Court has, therefore, again reviewed the interrogatories and answers with respect to which the parties are in disagreement.

"Interrogatory No. 55, with its 11 subdivisions (which referred back to question numbered 54), sought information respecting tests or studies made by claimant to determine the efficacy of the device under seizure. To this inquiry the claimant ultimately responded by stating that the tests referred to in interrogatory number 54 had been discontinued and terminated without producing any bases for conclusions therefrom. Under these circumstances, claimant will be deemed to have bound itself to an admission that NO such tests were ever made and, therefore, its affirmative answer to the inquiry in interrogatory number 54 shall be deemed amended to a negative.

"Claimant's answer to interrogatory number 9, upon which interrogatory number 10 is made to depend, was in the negative, i.e., claimant refused to admit that the seized devices were not an adequate and effective treatment for reducing weight, curing poor posture, firming and toning the body and providing a greater sense of well-being. And in its answer to interrogatory number 10, claimant affirmatively asserts the adequacy and efficacy of the device for the stated purposes when the device is used 'as a part of claimant's slenderizing plan which includes a program of reduced caloric input. It is generally recognized by authorities that a reduced caloric program with massage is effective and adequate for the purposes enumerated.' The Government contends that the foregoing is not responsive to its tenth interrogatory, which requires that the claimant provide in detail the facts which claimant contends to be true among the subdivisions of interrogatory number 9, and the names and addresses of all physicians and others having knowledge of such facts. Claimant still fails to answer interrogatory number 10 responsively. It must give the names and addresses of the persons referred to in the interrogatory, who have knowledge of the asserted adequacy and efficacy of the device.

"The Government has asked, in its interrogatory number 21, for an admission by the claimant that the seized mats, cards and folders related to the use of the seized devices, and in interrogatory number 22, in the event that the answer to number 21 was not unqualifiedly affirmative, that the claimant state in detail the facts supporting any negative or partial negative in the answer to question 21, with the names and addresses of persons having knowledge of such facts. Since claimant's answer to number 21 is an unqualified negative, it is obviously not an unqualified affirmative, and claimant will be required to answer number 22 with full responsiveness.

"Interrogatory number 34 seeks the names, addresses and professional qualifications of all physicians, other scientists or individuals having knowledge of every purpose, condition or disease which claimant contends may be adequately and effectively treated by the seized device. Claimant's purported response to this interrogatory is obviously unresponsive and must be modified and/or amended to a degree of complete responsiveness.

"Incorporating its present answer to interrogatory number 34, in lieu of answering interrogatory number 36 independently, is insufficient, and compliance must be made with the Court's previous directive respecting this interrogatory and its subdivisions.

"A similar requirement applies in the case of the answer to interrogatory numbered 37.

"Claimant's answers to interrogatories numbered 52 and 63 still fail to comply with the Court's previous directives. A fully responsive answer to question 63 will not be deemed a waiver by claimant of its contention that the documentary material seized does not constitute labelling.

"Libelant may present an order directing the claimant to supplement its answers to the Government's interrogatories in the manner and form, and to the extent and degree indicated by the foregoing views, such supplement to be served and filed within ten days after the date of said order, which shall also provide that failure of claimant's full compliance therewith shall entitle libelant to a judgment by default without further notice."

An order in accordance with the foregoing opinion was entered on 1–25–60, following which the claimant submitted further answers to the interrogatories. On 10–20–60, the claimant having consented to the entry of a decree, judgment of condemnation was entered, and the article was ordered released under bond for relabeling under the supervision of a representative of the Department of Health, Education, and Welfare. The claimant failed to file the bond as provided in the above decree and, accordingly, an order was entered on 1–20–61 directing that the article be turned over to the Food and Drug Administration.

DRUG AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

6447. Sodium dehydrocholate injection. (F.D.C. No. 45087. S. Nos. 26–251 R, 26–421 R.)

QUANTITY: 1,184 ampuls at Los Angeles and Downey, Calif.

SHIPPED: On 7–5–60 and 7–27–60, and subsequent thereto, from Philadelphia, Pa.

LABEL IN PART: "3 Ml Ampul Sodium Dehydrocholate N.F. 20%."

RESULTS OF INVESTIGATION: Analysis showed that the contents of the ampuls had a pH of 7.0 to 7.1, whereas, the National Formulary requires a pH between 8.5 and 9.5. Examination showed also that some of the ampuls contained varying amounts of suspended matter which, upon separation and analysis, proved to be dehydrocholic acid.

LIBELED: 11–10–60, S. Dist. Calif.

CHARGE: 501(b)—while held for sale, the quality of the article fell below the standard for *sodium dehydrocholate injection* set forth in the National Formulary; and 502(a)—the labeling of the article was false and misleading as applied to an article that purported to be of a quality represented in the standard established in the National Formulary for *sodium dehydrocholate injection*, but was not of such quality.

DISPOSITION: 12–5–60. Default—destruction.

6448. Rubber prophylactics. (F.D.C. No. 44836. S. No. 42–007 R.)

QUANTITY: 72 gross ctns., in pkgs. of 2 each, at Reno, Nev.

SHIPPED: 8–26–60, from Kansas City, Mo., by M & M Rubber Co.

LABEL IN PART: (Pkg.) "Package of Two Spartans Prophylactics."

RESULTS OF INVESTIGATION: Examination showed that 2.6 percent of the units examined were defective in that they contained holes.

LIBELED: 10–25–60, Dist. Nev.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess; and 502(a)—the label statement "For the Prevention of Disease" was false and misleading as applied to an article containing holes.

DISPOSITION: 12–15–60. Default—destruction.

6449. Rubber prophylactics. (F.D.C. No. 44713. S. Nos. 32–774/5 R.)

QUANTITY: 3 ctns., each containing 72 boxes of 2 cellophane-wrapped units each, and 3 ctns., each containing 48 3-unit boxes, at Middle Village, N.Y.

*See also No. 6442.

SHIPPED: 5–11–59 and 12–16–59, from Hanover, Germany, by Blausiegel Richter, Kaufer & Co., G.M.B.H.

LABEL IN PART: "Blausiegel BF 2 Spezial" and "Blausiegel Edel * * * B 3."

ACCOMPANYING LABELING: Leaflets printed in whole or in part in the German language.

RESULTS OF INVESTIGATION: Examination showed that the article (both lots) contained holes.

LIBELED: 7–15–60, E. Dist. N.Y.

CHARGE: 501(c)—the quality of the article fell below that which it was represented to possess; 502(a)—the label statement "For Protection Against Disease" was false and misleading; and 502(c)—the article failed to bear a label containing all words, statements, and other information required by, or under the authority of, the Act to appear on the label or labeling in the English language.

DISPOSITION: 9–12–60. Default—destruction.

6450. Rubber prophylactics. (F.D.C. No. 44887. S. Nos. 22–752/4 R, 31–084 R, 31–097/9 R.)

QUANTITY: 106 gross ctns., each containing 48 3-unit pkgs.; 106 gross ctns., each containing 48 3-unit plastic boxes; 83 gross ctns., each containing 144 single-unit plastic boxes; 53 gross ctns., each containing 48 foil-wrapped 3-unit plastic boxes; and 53 gross ctns., each containing 48 foil-wrapped 3-unit pkgs., at Akron, Ohio.

SHIPPED: 8–26–60, from Oklahoma City, Okla., and 8–16–60 and 8–23–60, from Dallas, Tex. These were return shipments.

LABEL IN PART: (Ctn.) "Checks Deluxe Thin Prophylactics [or "Three's Gladiator Prophylactics Transparent Thins Reservoir End" or "Three's Poket-Pak Silver Coin Package Deluxe Thin Prophylactics"] * * *March Rubber and Plastics Co., Inc., Akron 6, Ohio."

RESULTS OF INVESTIGATION: Examination showed that the article was defective in that it contained holes.

LIBELED: 9–15–60, N. Dist. Ohio.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported to possess.

DISPOSITION: 10–11–60. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

6451. Miracle Special Tonic. (Inj. No. 394.)

COMPLAINT FOR INJUNCTION FILED: 12–5–60, E. Dist. Mich., against Lee Anna Robinson, t/a Lee Anna Robinson Co., Detroit, Mich.

CHARGE: The complaint alleged that the defendant was engaged in the business of manufacturing, preparing, packing, labeling, selling, and distributing in interstate commerce, an article of drug designated as "Lee Anna Robinson's Miracle Special Tonic"; that investigation had disclosed that the article was

*See also Nos. 6441, 6442, 6445–6449.

made by boiling a mixture of dry herbs and water for two hours and then filtering the mixture through a silk cloth, cooling it, and packing it into 12-oz. bottles; and that the article, when introduced into interstate commerce, was misbranded under 502(a) in that its labeling was false and misleading since the article was represented as an adequate and effective treatment for high blood pressure, constipation and gas, stomach ulcers, sugar diabetes, swelling, stiff joints and muscles, bronchitis and asthma, whereas, the article was not an adequate and effective treatment for such diseases and conditions, and was worthless for any disease or condition of man or other animals.

The complaint alleged also that the defendant was well aware that her activities were violative of the Act; that a hearing had been held on 2–18–60, pursuant to Section 305, at which time the defendant was warned that the article was violative of the Act; and that despite such warnings, the defendant continued to introduce the article into interstate commerce.

DISPOSITION: 12–16–60. The defendant having consented, the court entered a decree of permanent injunction enjoining and restraining the defendant from commission of the acts complained of.

6452. Coach-Aid N.B. pills and Coach-Aid Stim-O-Stam Food Supplement tablets. (F.D.C. No. 45075. S. Nos. 14–963/4 R.)

QUANTITY: 19 cans of *Coach-Aid N.B. pills* and 60 cans of *Coach-Aid Stim-O-Stam Food Supplement tablets* at Cincinnati, Ohio.

SHIPPED: 9–10–59, from Little Rock, Ark., by Health Research, Inc.

LABEL IN PART: (Can) "Coach-Aid Special Formula N.B. Pills (bioflavonoids with C) 500 Pills Capillary tablets to improve resistance to bruising, bleeding, and the 'common cold.' * * * Distributed by Health Research, Inc. Hot Springs, Ark. 90802 * * * Each tablet contains: Ascorbic Acid (Vitamin C) . . . 200 mg. Purified Hesperidin (Bioflavonoids) 200 mg." and "Coach-Aid Stim-O-Stam Food Supplement 1000 Tablets Perfected to add physical endurance and lessens muscle soreness. Replenishes lost body salt. * * * Distributed by Health Research, Inc. Hot Springs, Ark. Contents: A mixture of alkali, metal phosphates contained in natural body salts. Active Ingredients: Phosphate–PH 6.5–7.0."

ACCOMPANYING LABELING: Leaflets entitled "Coach-Aid Stim-O-Stam" and "Announcing Coach-Aid Stim-O-Stam Food Supplement."

LIBELED: 11–2–60, S. Dist. Ohio.

CHARGE: *Coach-Aid N.B. pills.* 502(a)—when shipped, the labeling of the article contained false and misleading representations that it was an adequate and effective treatment for improving capillary resistance, overcoming normal capillary permeability, strengthening capillary walls, reducing severity of bruises, for increased absorption of iron from food, and for resistance to the common cold.

Coach-Aid Stim-O-Stam Food Supplement tablets. 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective as a treatment for adding physical endurance, lessening muscle soreness, improving physical efficiency, and aiding in preventing fatigue.

DISPOSITION: 12–12–60. Default—destruction.

6453. Lecithin granules. (F.D.C. No. 44722. S. No. 49–968 R.)

QUANTITY: 37 cases, containing 12 8-oz. btls. each, and 18 cases, containing 6 1-lb. btls. each, at Lubbock, Tex., in possession of Plains Cooperative Oil Mill, Inc.

SHIPPED: 3–29–60 and 5–12–60, from Chicago, Ill., by Central Soya Co., Inc.

LABEL IN PART: "RG LECITHIN * * * Granules * * * a dietary source of choline, inositol and phosphorus * * * A natural food product extracted from soybeans * * * contains both linoleic and linolenic acids * * * Mfd. by and packed for Central Soya Company, Inc., Chemurgy Division."

ACCOMPANYING LABELING: Reprints of articles entitled "Serum Cholesterol Reduction With Lecithin" and "Lecithin and Health."

RESULTS OF INVESTIGATION: The above-mentioned reprints were purchased by the dealer for use in promoting the sale of the articles.

LIBELED: 7–28–60, N. Dist. Tex.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was adequate and effective to regulate and to lower the blood cholesterol;

502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that the article was adequate and effective for the prevention and treatment of cardiovascular diseases; arteriosclerosis; hypercholesterolemia; and hyperlipemia; that it was capable of lowering serum cholesterol in the blood and excessive blood fats; and that the article was adequate and effective for the prevention and treatment of diseases and conditions of the heart, liver, kidneys, circulatory diseases, coronary thrombosis, high blood pressure, arthritis, diabetes, and mental ills; that it was capable of lowering cholesterol in the blood; and that it would promote good health, high bodily efficiency, and prolong the length of active life.

DISPOSITION: 12–7–60. Default—destruction.

6454. Honey Al-Fa Tea. (F.D.C. No. 44913. S. No. 23–315 R.)

QUANTITY: 29 16-oz. btls. and 22 32-oz. btls. at Oklahoma City, Okla.

SHIPPED: 8–1–60 and 9–12–60, from Dallas, Tex., by Honey Al-Fa Pharmaceutical Co.

LABEL IN PART: "Concentrated Honey Al-Fa Tea * * * Homogenized * * * Especially pressed, extracted, and brewed from rich Alfalfa components. Also contains Proteins, Amino Acids (Arginine, Histidine, Lysine, Humin, Saponin, and natural enzymes) Plus Pure Bee Honey and Apple Cider Vinegar."

ACCOMPANYING LABELING: Leaflets entitled "A Reader's Digest Reprint Concentrated Honey Al-Fa Tea" and "For Your Vitamins Concentrated Honey Al-Fa Tea."

LIBELED: 9–27–60, W. Dist. Okla.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for arthritic conditions; rheumatic conditions; gout; ulcerated stomach; migraine headaches; hay fever; muscle cramp; sinusitis; alcoholism; and bed wetting; that use of the article would prevent illness; produce healthy offspring; and cause one to live to a ripe old age.

The libel alleged also that the article was misbranded under the provisions of the Act relating to foods as reported in notices of judgment on foods.

DISPOSITION: 12–5–60. Default—destruction.

6455. Vanul. (F.D.C. No. 44911. S. No. 32–780 R.)

QUANTITY: 121 16-oz. btls. at New York, N.Y.

SHIPPED: 8–23–60, from Cedar Grove, N.J., by Vanguard Pharmaceutical Corp.

LABEL IN PART: "VANUL A licorice-peppermint flavored aqueous suspension of vegetable mucilage with tincture of belladonna. * * * Each tablespoonful (15 cc) dose contains: Vegetable mucilage 2 cc Tincture of belladonna 0.3 cc Fluidextract of glycyrrhiza 0.35."

ACCOMPANYING LABELING: Brochures entitled "VANUL New discovery in the treatment of Gastric and Duodenal Ulcers"; counter signs reading in part "Ulcers Adequate Treatment . . ."; and window signs reading in part "Results: Total of 408 Case Histories . . ."

LIBELED: 10–7–60, S. Dist. N.Y.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for gastric and duodenal ulcers.

DISPOSITION: 11–3–60. Default—destruction.

6456. Exultation of Flowers. (F.D.C. No. 44884. S. No. 41–718 R.)

QUANTITY: 11 2-oz. btls. and 5 16-oz. btls. at Oakland, Calif.

SHIPPED: On an unknown date, from Nairn, Scotland.

LABEL IN PART: "Exultation of Flowers. Potencies of: Oak, Eucalyptus, Water Crowfoot, Sunflower, Bean, Daisy, Birch, Mimosa, and 44 other flowers. Concentrate for this product made in Scotland."

ACCOMPANYING LABELING: Booklets entitled "Exultation of Flowers World Significance"; and 3 different colored leaflets, all headed "Exultation of Flowers Prepared by Elizabeth Bellhouse," and reading in part: (white) "Directions for Human Use," (tan) "Its Use for Animals," and (blue) "Its Use for Domestic Pets."

LIBELED: 9–12–60, N. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was adequate and effective for human use for the treatment of colds, flu, sore throat, extreme pain when death threatens or in case of accident, wounds, burns, removal of accumulated poisons and impurities, catarrhal discharge, diarrhea, sleeplessness, upset conditions, and to increase the flow and quality of breast milk and make it possible to breast feed for as long as desired; that use of the article by humans would result in clearer skin, stronger nails, healthier hair, brighter eyes, increased vitality, longer life expectancy and improved health; and that the article would be effective for use as a contraceptive; and that the article was adequate and effective for the treatment of all conditions and diseases of all farm animals and domestic pets; and 502(b)(1)—when shipped and while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: 10–20–60. Default—destruction.

6457. Wonder Ease massage device. (F.D.C. No. 44906. S. No. 25–430 R.)

QUANTITY: 10 devices at Long Beach, Calif.

SHIPPED: During 1957–1960, from Denver, Colo., by Cyclo Manufacturing Co.

LABEL IN PART: (Metal plate on device) "Cyclo Mfg. Co., Denver, Colo. Wonder Ease Model 5."

ACCOMPANYING LABELING: Pamphlets entitled "Wonder Ease Plan for Better Living"; booklets described as training manuals; brochures entitled "Wonder Ease Plan for Better Living"; and reprints of newspaper articles which are a part of the brochure entitled "Wonder Ease Plan for Better Living."

RESULTS OF INVESTIGATION: Investigation indicated that the article consisted of a motor to which were attached two soft rubber discs. Vibration was reportedly obtained by eccentric rotation of these two discs in a vertical plane. The motor was attached to a tubular aluminum frame in such manner that it could slide up or down so that different areas of the body could be reached for massage. The motor could also be removed from the frame and held in the hand while massaging parts of the body which could not be reached while the motor was attached to the frame. The aluminum frame holding the motor was mounted on a door by means of clamps and suction cups. For massaging the feet the motor was placed on the floor and the feet placed against the vibrator.

LIBELED: 9–23–60, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for relieving tensions, nagging aches and pains of chronic arthritis, rheumatism, bursitis, and related ailments; reducing and controlling weight; trimming off unwanted inches; spot reducing; and firming and toning the figure.

DISPOSITION: 10–21–60. Default—one device delivered to Food and Drug Administration; the remainder destroyed.

6458. Contour chair. (F.D.C. No. 44880. S. No. 21–437 R.)

QUANTITY: 13 devices at Cleveland, Ohio.

SHIPPED: Between 5–3–60 and 8–16–60, from St. Louis, Mo., by Contour Sales, Inc.

LABEL IN PART: (Metal tag on top rear of some chairs) "Contour Chair with Viverator Lounge Co., Inc. St. Louis, Mo. * * * 110–120 volt AC 0.55 Amp. 55 Watt."

ACCOMPANYING LABELING: Leaflets entitled "Contour's Progressive Relaxation * * * New 'No Drug' Way to 'Tranquilize'," "Are you getting the Plus Benefits," "You—Mr. American Businessman," "Ask Your Doctor," and "Sale Contour Chairs"; folders entitled "The Original Contour Chair Lounge"; and placards entitled "10 Big Reasons You Should Buy Contour."

RESULTS OF INVESTIGATION: Investigation indicated that the article was an upholstered lounge or reclining-type chair which was adjustable to several positions and contained an electric motor capable of providing controlled degrees of vibration. Some of the units might also have been equipped with a rheostat-controlled heating element.

LIBELED: 9–14–60, N. Dist. Ohio.

CHARGE: 502(a)—when shipped, the labeling of the article contained false and misleading representations that the device was an adequate and effective treatment for reducing surface tension; removing tension by concentrating heat in the nerve centers of the back and thighs; improving posture

and health; relieving backaches, burden on the heart, nervous exhaustion, arthritis, and rheumatism; normalizing circulation; increasing energy and strength; overcoming conditions which may lead to chronic invalidism; aiding in relieving acute infectious diseases, cardiac maladies, and high blood pressure; and quieting the nervous system.

DISPOSITION: 9–29–60. Consent—claimed by Contour Chairs of Cleveland, Inc., and relabeled.

6459. **Relax-4-Life chairs.** (F.D.C. No. 45046. S. No. 53–281 R.)

QUANTITY: 11 chairs at Concord, N.H., in possession of Associated Sales, Inc.

SHIPPED: 4–4–60 and other unknown dates, from Santa Rosa, Calif.

ACCOMPANYING LABELING: Display banners reading in part "Soothing Deep Heat and Massage Relaxes Tension and Nervousness Increases the Circulation Decreases the Pain of Arthritis and Bursitis Clinically Proven . . ." and "Orthopedically Designed to Give You Healthful Economical Clinically Proven Natural Relief from Arthritis—Bursitis—Tension—Backache—Headache."; and brochures entitled "The Relax-4-Life chair presents."

RESULTS OF INVESTIGATION: The article was an adjustable, reclining, upholstered chair containing polyfoam cushioning and an electric motor capable of providing vibrations. Individual units could also be equipped with heating elements. The accompanying labeling described above was prepared by the dealer.

LIBELED: 10–17–60, Dist. N.H.

CHARGE: 502(a)—the labeling accompanying the article, while held for sale, contained false and misleading representations that the article was an adequate and effective treatment for relieving nervous tension, pains in the back and spinal areas, headaches, and poor circulation, easing work load on the heart, alleviating or decreasing pain problems of arthritis, rheumatism, and bursitis, and improving one's health and adding years to one's life.

DISPOSITION: 12–15–60. Associated Sales, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the display banners and brochures be destroyed and that the chairs be returned to the claimant.

DRUG FOR VETERINARY USE

6460. **Cod liver solubles.** (F.D.C. No. 44733. S. No. 36–826 R.)

QUANTITY: 24 55-gal. drums at Reading, Pa.

SHIPPED: 5–17–60, from St. John's, Newfoundland, Canada.

LABEL IN PART: "Newfoundland Cod Liver Solubles For Poultry Feeding Only * * * Ingredients: The Aqueous Phase of Cod Livers."

ACCOMPANYING LABELING: Pamphlet entitled "Cod Liver Solubles A Proven Hematinic for Aplastic Anemia."

LIBELED: 7–20–60, E. Dist. Pa.

CHARGE: 502(a)—while held for sale, the labeling accompanying the article contained false and misleading representations that the article was adequate and effective for the prevention and treatment of aplastic anemia in chickens.

DISPOSITION: 11–30–60. Consent—claimed by J. C. Ellis & Co., Ltd., St. John's, Newfoundland, and relabeled.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (6446) Seizure contested. Contains interrogatories, decisions, and opinion of the court.

[2] (6451) Injunction issued.

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